MISSOURI COMMISSION ON PATIENT SAFETY

Report Presented to
Governor Bob Holden
July 2004

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Missouri Commission on Patient Safety
July 2004

Executive Summary

The Institute of Medicine (IOM) galvanized public attention on patient safety with its November 1999 report, *To Err Is Human*, which cited "preventable medical errors" as the eighth-largest cause of death in this country. The study estimated that between 44,000 and 98,000 Americans die needlessly each year from medical errors in hospitals. Those figures translate into an estimated 900 to almost 2,000 Missouri deaths each year from medical errors in hospitals.

The IOM report projected the national cost for medical errors at between $17 billion and $29 billion annually, with extra treatment expenses for injuries amounting to half of the total costs and lost patient income and productivity accounting for the remainder. Those totals do not include private practice and other outpatient settings, where about two-thirds of medical errors likely occur.

The impact of the IOM report, subsequent patient safety work on several fronts and Missouri's growing crisis over professional liability premiums culminated in September 2003 when Governor Bob Holden appointed the Commission on Patient Safety to recommend how to improve medical outcomes and prevent errors that lead to litigation. The 16-member commission included seven physicians, including an HMO medical director; a hospital administrator; two hospital patient safety specialists; a registered nurse; a general consumer; two attorneys; and representatives of the Missouri insurance and health/senior services departments. Officials from the state licensing boards for physicians, pharmacists and nurses served in ex-officio capacities.

The commission met in daylong sessions twice a month until May 2004 and heard testimony from an array of national and state authorities on patient safety. The commission determined:

- **No focal point in Missouri coordinates safety activities among healthcare organizations and professionals and mobilizes government, business and academia to serve the interests of patients**. The IOM report clearly states the need for a clearinghouse, especially for disseminating information on the tools for reducing adverse medical events. However, the movement is fragmented in Missouri. Most activity centers among larger institutions, but the commission found few resources available — even nationally — for private practice and other outpatient settings.

- **To truly improve patient safety, healthcare organizations and professionals must focus on developing healthcare delivery systems that, by design, work to prevent adverse events from happening.** Most adverse events result from failures in those systems, not the willful or negligent conduct of an individual.

- **Patients have access to few, if any resources for making safer choices in healthcare, which can limit their ability to improve the outcome of their own treatment.**

- **The current legal liability climate, retribution against individuals for reporting errors and other barriers have a chilling effect on the willingness of healthcare organizations, professionals and other staff to discuss and report adverse events, either within their own institutions or to external authorities.**

- With no standards in place, **purchasers of healthcare have not identified patient safety** — and, in a related manner, quality — **as a priority when contracting for services on behalf of employees and other consumers**.

The commission concludes that, in the words of a 2001 IOM report, "the healthcare environment should be safe for all patients, in all processes, all the time."

The commission urges **all Missouri healthcare organizations to adopt patient safety protocols — or minimum standards** — that provide for:

- Disclosing adverse medical events and outcomes to patients.
- Identifying an advocate and providing counseling for patients affected by adverse events or outcomes.
- Establishing internal patient safety reporting and analysis of adverse events and near misses that allow improving healthcare delivery systems to avoid future errors.
- Adopting best practices and technological advances that reduce the opportunity for adverse events.
- Designating a patient safety officer for each healthcare setting.
- Protecting the job status of any healthcare professional or employee who in good faith reports conditions or events that jeopardize patient safety.

The commission recommends that Missouri establish a private **Missouri Center for Patient Safety** to provide leadership and serve as a clearinghouse for best practices, data collection and analysis, professional curriculum development and consumer resources. This private center can work as a partner with public health, insurance and other regulatory agencies.

The adoption of these protocols, best practices and other systemic improvements will allow insurers and other payers — including the largest, state government — to provide **contract incentives for those healthcare organizations and professionals that emphasize safety**. The commission also **endorses medical malpractice premium discounts for those that participate in recognized patient safety activities**.

To create the internal environment for healthcare organizations to learn from adverse events and improve delivery systems, **Missouri should update its "peer review" laws** — which shield information from legal discovery — **to broaden protections and allow participation by non-healthcare staff.**

The commission also recommends that the legislature and elected officials address issues — many of them long identified — to **better protect the public from the minority of unsafe healthcare organizations and professionals.**

To implement this report's recommendations, **the commission urges elected officials and the General Assembly to work with Missouri's healthcare organizations and professionals, consumer groups and state agencies to improve healthcare delivery systems, expand peer review statutes and provide incentives for patient safety activities.**

Recommendations

All Missouri healthcare organizations and professionals should be educated on safety and encouraged to adopt protocols and processes for improving the safety of patients. The Missouri Commission on Patient Safety recommends all Missouri healthcare organizations:

- Establish guidelines for the disclosure of adverse events and outcomes to patients.
- Identify an advocate and counseling resource for any patient impacted by an adverse event or outcome.
- Create a culture of safety focusing on a system-oriented approach to reducing patient harm.
- Establish internal patient safety reporting systems for adverse events and near-misses.
- Use the tools of patient safety.
- Develop awareness and promote implementation of best practices.
- Designate a patient safety officer appropriate to each healthcare setting.
- Protect any healthcare professional or employee who, in good faith, reports conditions or events that jeopardize patient safety.
- Promote evaluation and implementation of technological advances that enhance patient safety.
- Establish an ongoing review of adequate availability of healthcare professionals and staff training.

A new private Missouri Center for Patient Safety should act as a leadership vehicle for patient safety improvements and be a resource for healthcare organizations, professionals and consumers. It should:

- Provide leadership for improvements in patient safety.
- Develop and promote minimum patient safety standards for healthcare organizations and professionals.
- Establish a "consumer coalition" to make the patient a more active, better-informed member of the treatment team.
- Act as a research institute for the collection, analysis and sharing of patient safety data.
- Promote the use of best practices in all healthcare settings.
- Assist healthcare organizations in developing counseling resources and support groups for patients and facilities affected by adverse events and outcomes.
- Develop and promote undergraduate, graduate and continuing education curricula on patient safety through an "education coalition."
- Assist outpatient settings, such as smaller physician practices, in developing patient safety models that adapt to their size.
- Develop and implement award/recognition programs for outstanding patient safety achievements.
- Adopt a common terminology and data sets for patient safety in Missouri.
- Act as the state patient safety organization if federal legislation passes.

A consumer coalition in the Missouri Center for Patient Safety should help empower patients to play a central role in their own healthcare and take precautions for their well-being in healthcare settings.

- Conduct consumer research to better document patient needs for information and concerns about safety.
- Develop easily accessible, reliable educational materials – especially interactive and Internet-based tools.
- Disseminate information on how consumers can detect and prevent conditions that endanger their safety.
- Work to make more information available to patients about choices in healthcare professionals, their safety records and quality of care.
- Support other consumer healthcare advocacy organizations and complaint investigation activities of state agencies.
- Speak forcefully for patients' interests within Missouri Center for Patient Safety.

Missouri should provide statutory protection for patient safety activities to encourage healthcare organizations and professionals to voluntarily report information and participate in the peer review/quality improvement process. The General Assembly should:

- Create protections for information shared among healthcare organizations and professionals that is designed solely for improving patient safety and healthcare delivery systems.
- Expand the qualifications of members on peer review/patient safety committees to allow full participation by licensed healthcare professionals not listed in the statute, non-licensed professionals like risk managers and other employees who play key roles in safety improvements.
- Eliminate cumbersome requirements for appointing peer review committees.
- Protect patient safety data, documents and information reported to the Missouri Center for Patient Safety from use in civil, judicial and administrative proceedings.
- Protect the job status of healthcare professionals and organization employees from reprisal for reporting errors internally and to the Missouri Center for Patient Safety.

Missouri healthcare schools and licensing agencies should establish curricula of key patient safety concepts for the primary training and continuing education of professionals.

- The Missouri Center for Patient Safety's educational coalition should work with accreditation agencies responsible for establishing healthcare professionals' education requirements to incorporate key patient safety concepts into the curricula.
- The Missouri Center for Patient Safety's education coalition should promote patient safety compentency of healthcare professionals through continuing education activities.
- The Missouri Center for Patient Safety's education coalition should promote improved communication among healthcare professionals and with patients at all levels of healthcare delivery.

Legislators and elected officials should work with healthcare organizations, professionals and regulatory agencies to evaluate and address effective regulation of licensees in the interest of patient safety.

- The state should begin licensing 'free-standing' medical specialty facilities that provide diagnostic services and perform such procedures as diagnostic imaging, heart procedures, gastrointestinal, endoscopy and kidney dialysis.

- The General Assembly, where appropriate, should allow licensing agencies to improve investigations of unsafe healthcare professionals, and take disciplinary action when it is evident that the provider was reckless, incompetent, impaired, negligent or abusive.

Missouri organizations and professionals should have incentives to participate in proven patient safety activities.

- Healthcare payers should include incentives to foster patient safety initiatives in contracts for healthcare services.

- Liability insurers, including the new Missouri Medical Malpractice Joint Underwriting Association (JUA), should provide discounts for healthcare professionals and organizations that participate in patient safety activities.

- The Missouri Center for Patient Safety should sponsor award programs to bring public recognition to successful healthcare organizations and increase the viability for patient safety programs statewide.

Setting patient safety expectations for all healthcare organizations in Missouri

Commission recommendation: All Missouri healthcare organizations and professionals should be educated on safety and encouraged to adopt protocols and processes for improving the safety of patients.

Little uniformity exists across Missouri's healthcare organizations on expectations for protecting patient safety and reducing patient harm from adverse events. Organizations and professionals have no common benchmarks, and patients and purchasing groups have no assurances that providers are observing minimum thresholds for safeguarding care, including support services if errors occur.

Among current licensing and accreditation programs:

- The state Department of Health and Senior Service's licensure of hospitals, ambulatory diagnostic centers and nursing homes does not explicitly set standards for commonly accepted patient safety activities.
- Other Missouri healthcare organizations and medical providers, such as physician offices and freestanding surgical centers, aren't subject to the licensing and regulation required of hospitals.[1]
- Federal standards for Medicaid and Medicare programs do not specify patient safety activities.
- The private Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has adopted standards requiring some patient safety activities, including specific precautions like hand washing and procedures like root cause analysis, for its members. While 112 of 150 Missouri hospitals – 75 percent – are accredited,[2] the rate of accreditation is much lower for outpatient settings, where more errors and more complex medical procedures are occurring. In April 2004, the Robert Graham Center for Policy Studies in Family Practice and Primary Care – affiliated with the American Academy of Family Physicians – reported that 68 percent of paid, error-related malpractice claims resulted from care in outpatient settings and caused more deaths than in hospitals.[3]

The 1999 IOM report, *To Err is Human*, concluded, "accreditation and licensure programs for healthcare organizations and providers have been promoted as 'good housekeeping seals of approval,' yet they fail to provide adequate assurance of a safe environment. Reducing medical errors and improving patient safety are not an explicit focus of these processes. Even licensed and accredited organizations may have implemented only rudimentary systems and processes to ensure patient safety."[4]

To Err is Human bluntly stated that healthcare is "a decade or more" behind other high-risk industries like aviation, nuclear power and general industry in ensuring basic safety.[5] Among the medical specialties, only anesthesiologists have emerged in the front ranks of safety. Since the mid-1980s, they have reduced their error rate by almost 90 percent and reduced their liability insurance premiums nationally despite inflation.[6]

The IOM report specifically recommended that the commission setting standards for patient safety among healthcare organizations and professionals, which in turn helps set expectations for consumers and purchasers.[7]

Based on public testimony and the literature on patient safety, the Missouri Commission on Patient Safety recommends that all Missouri healthcare organizations:

Patient-centered protocols

- **Establish guidelines for the disclosure of adverse events and outcomes to patients.**

Despite the best intentions and efforts of healthcare personnel, medical errors and adverse events do occur. Numerous studies have shown that patients need open communication with their physician after adverse events that result in injury. Partly to manage their own care and partly to protect others, patients want information about what happened, why the adverse event occurred, how to correct or manage it and how this error will not occur again. Perhaps more importantly, patients also seek emotional support from their caregivers; often all they want to hear is an apology.[8]

Healthcare organizations and professionals resist disclosure policies because they — and/or their legal counsel — fear dramatic increases in liability costs, but research strongly suggests that patients place higher value on honesty and information rather than litigation.[9]

Many leading healthcare groups have endorsed disclosure when adverse events occur. JCAHO says providers should explain the outcome of any treatments or procedures to the patient and, when appropriate, the family if the outcomes differ significantly from anticipated events. The National Patient Safety Foundation (founded by the American Medical Association) urges all healthcare professionals and institutions to deal honestly with patients and acknowledge that the patient and the family are entitled to prompt explanations of how the injury occurred and its short and long-term effects. Both IOM reports — *To Err is Human* and *Crossing the Quality Chasm* in 2001 — call for increased transparency and disclosure in the healthcare industry.

Numerous studies support the need for disclosure of errors. A review of closed claims in Florida, more than 60 percent of newborn-injury lawsuits were motivated by the suspicion of cover-up, the need for information or the desire for revenge.[10] Healthcare professionals and organizations can avoid malpractice cases through disclosure or an apology; when patients receive neither, they feel suspicious, angry and doubly wronged, eventually seeking legal counsel.[11]

More importantly from a patient's perspective, healthcare organizations and professionals have an ethical, even a contractual obligation to provide disclosure. Patients need complete access to all information about their own bodies so they can participate in their own care and make intelligent decisions, including compliance with future treatment. The phrase "Nothing about me, without me" — a rallying cry for patient safety advocates around the world, including the Institute of Medicine in its report — underlies the obligation to disclose all information to patients regarding their healthcare.

- **Identify an advocate upon admission and counseling resource for any patient impacted by an adverse event or outcome.**

Groups such as the National Patient Safety Foundation (NPSF)[12] and, locally, Missouri Watch[13] recommend an advocate or representative for patients and/or their families in healthcare settings. This person would help the patient navigate the healthcare system and address concerns as they develop. Many hospitals have ombudsmen, social workers or patient advocates/representatives on staff. NPSF recommends training them about safety and medical errors to effectively advocate and ease communication for patients and families. NPSF also recommends publicizing their services to patients and families upon admission.

Advocates can provide necessary services in the hospital, but also can serve as a tremendous asset for patients in a nursing home or a private practice setting. They allow the healthcare professional to maintain the focus on providing clinical services and empower patients by helping them learn more about their condition.

Systems-focused protocols

- **Create a culture of safety focusing on a system-oriented approach to reducing patient harm.**

Although five years have passed since the IOM report that magnified attention on patient safety, barriers to improvements still abound. As the IOM noted, among the most important barriers is the lack of awareness

about how commonly errors occur daily in all healthcare settings. Often errors are not reported, even internally, because healthcare professionals fear they will be punished through litigation, loss of license, loss of employment, reprisal in the workplace and damage to reputation.

To help overcome this barrier, healthcare organizations can create a "culture of safety," which British researcher James Reason — a leading theorist on patient safety — identified as having four critical components: 1) a reporting culture in which persons report errors and near-misses; 2) a just culture that encourages, even rewards, persons for providing essential safety information without penalty; 3) a flexible culture that responds to changing demands; and 4) a learning culture that draws the right conclusions from safety information.[14]

A learning culture suggests that when safety concerns or hazards are reported, healthcare organizations find ways to reduce these hazards. Using a "systems-oriented approach," organizations improve the system of care (work environment, equipment, communication, training, rules, procedures, scheduling and staffing) rather than look to simply blame individuals. As we all know, "to err is human." Replacing or disciplining an individual will not correct the conditions that permitted the event to happen. Healthcare organizations and professionals cannot change the human condition, but they can design working conditions that minimize the likelihood that errors will occur or at least affect the patient adversely.

Simplifying and standardizing work are well-known safety measures used heavily in other high-risk settings like aviation and nuclear power. These industries have a common bond: they cannot afford to fail – without major loss of life. Even general business owners – which operate in a legal, no-fault climate — have improved workplace safety so dramatically that injury reports in Missouri dropped 18 percent from 2001 to 2003.[15]

Healthcare must adopt these same approaches to better serve its patients.

- **Establish internal patient safety reporting systems for adverse events and near-misses.**

Only with such reporting systems can healthcare organizations and professionals learn from all mistakes and prevent them from recurring within their facilities.

High-risk industries like aviation, nuclear power and petrochemicals uniformly established reporting systems for adverse events and near-misses. These systems give front-line workers the ability to report unsafe conditions and those industries a way to analyze safety data and use it to reduce hazards.

Among the best examples is the Aviation Safety Reporting System (ASRS), established in 1975 by the Federal Aviation Administration (FAA) and the National Aeronautics and Space Administration (NASA). The ASRS collects, analyzes and responds to aviation safety incident reports to reduce the likelihood of accidents. All reports sent to ASRS are kept strictly confidential and stripped of identifying information. Confidentiality has never been breached although ASRS has received more than 300,000 reports. If a pilot or other aviation worker self-reports, the FAA will not use ASRS information against the person in disciplinary actions. The FAA also will waive fines and penalties under most conditions for unintentional violations of federal aviation regulations that are reported.[16]

Voluntary reporting systems also exist in healthcare, but huge gaps remain. MedMARx is an Internet-based, anonymous, voluntary system for hospitals to report medication errors, administered by the United States Pharmacopeial Convention, Inc. MERS-TM (Medical Event Reporting System for Transfusion Medicine) is an event reporting system developed for transfusion services and blood centers. JCAHO encourages hospitals to voluntarily report sentinel events to the accrediting body's own system. The Food and Drug Administration's (FDA) program operates MedWatch for reporting serious reactions and problems with regulated drugs, biologics, devices and dietary supplements.

Most hospitals in the United States have some type of paper-based incident reporting system. Hospitals with robust patient safety programs are supplementing or replacing these systems with telephone hotlines and Internet-based electronic reporting.

Staff should use internal reporting systems to report near-misses and adverse events related to medications; complications from procedures and tests; equipment failures; skin breakdowns; infections; patient misidentification; and falls, among others. For example, staff should report actual events or near-misses that involve the wrong drug, wrong patient, wrong site for surgery, wrong dosage or wrong procedure.

In response to those reports, healthcare organizations should perform root causes analyses (see below) on priorities and analyze data for trends and their causes to identify improvements. These systems should provide timely feedback about root causes and solutions to staff.

- **Use the tools of patient safety.**

High-risk industries like nuclear power and aviation have developed tools to analyze the causes of accidents as part of their error prevention approach. Healthcare organizations have begun to borrow these tested techniques to emulate the success of these industries.

Root cause analysis (RCA) — a retrospective approach to error analysis — has been used to investigate major industrial accidents.[17] It is a structured process after an adverse event or near-miss to find out what happened, why it happened and how to prevent it from recurring. Root cause analysis teams draw on many disciplines, contain frontline workers most familiar with the incident and aim for impartiality.[18] As a response to "sentinel events" — mishaps involving death or serious injury — JCAHO expects accredited healthcare organizations to perform RCA and make improvements. Other healthcare systems such as the Veteran's Administration have expanded the use of RCA to near-misses that could have caused catastrophic harm to the patient.

Failure mode and effect analysis (FMEA) provides a systematic method of identifying and preventing problems before they occur.[19] Engineers in aviation, nuclear power, aerospace, chemical processing, food processing and automotive industries have used this process for more than 30 years.[20] While RCA looks at an actual occurrence, FMEA tries to prevent accidents by brainstorming possible future failures, assessing their probability and developing prevention strategies. JCAHO expects that accredited healthcare organizations will perform such risk assessments to identify system vulnerabilities.

Crew resource management (CRM) is interdisciplinary teamwork training developed in the aviation industry. In the late 1980s, the aviation industry realized the main cause of commercial airline crashes was not the technical incompetence of pilots and crews or mechanical failure. Instead, 70 to 80 percent of fatal accidents resulted from teamwork failures among the crew. In response, federal regulators required commercial air carriers to institute team training for airline pilots and crews.[21] The training teaches about the limits of human performance, fatigue and stress, the nature of human error and countermeasures to mistakes, including pre- and post-event briefings, checklists, cross-checking communication, peer monitoring, crisis response and team decision-making. Data within the aviation industry supports CRM's effectiveness in reducing accidents.[22] Between 1950 and the early 1990s, the airline industry reduced its fatality rate by more than two-thirds; in 1998, no commercial aviation deaths occurred while a total of 19 took place in 2002 and 2003.[23]

Recently, CRM has been adapted for use in the healthcare industry. CRM training has been offered in high-risk areas at Vanderbilt University Medical Center, University of Missouri Healthcare, Kaiser Permanente, the Veterans Administration hospitals and the nation's military healthcare system.

Human factors engineering tries to optimize how people use and interact with technology by encouraging systems design to fit human limitations and gathering data on the user's "hidden needs" and the interaction between man and machines.[24] One tool from human factors engineering provides for testing products,

machines and information technology for ease of use — which should become a requirement of the purchasing process within healthcare organizations.

While cutting their fatality rate from two per 10,000 surgeries to one per 200,000 to 300,000 applications over 15 years, anesthesiologists used many of these tools within a culture of safety. They acknowledged a serious problem, shared information, standardized procedures and addressed the issues of fatigue and inadequate training. For example, different manufacturers designed controls that worked in exactly opposite ways to increase or reduce the flow of anesthetics, dramatically increasing the chances for human error. Once notified, the manufacturers adopted standardized dials, and the error rate fell.

- **Develop awareness and promote implementation of best practices.**

Few, if any, justifications exist for healthcare organizations and professionals to not employ what the nation's leading safety proponents consider "best practices" in the clinical setting.

Nationally, many groups help healthcare organizations discover best practices to improve patient safety. This list includes but is not limited to the federal Agency for Healthcare Research and Quality (AHRQ), the private National Quality Forum, the JCAHO, the federal Medicare quality improvement organizations, the Institute for Healthcare Improvement, the Veteran's Administration National Center for Patient Safety, the Institute for Safe Medication Practices, the National Patient Safety Foundation and a host of societies and associations for healthcare organizations, physicians, nurses, pharmacists, therapists and other professionals.

In July 2001, AHRQ produced "Making Healthcare Safer: A Critical Analysis of Patient Safety Practices," a 668-page document that rates best practices on adverse drug events, infections, pressure ulcers, falls, venous thromboembolism, gastrointestinal bleeds, patient identification, crew resource management, inter- and intra-hospital transport, antibiotics, pain management, vaccine effectiveness, informed consent, bar coding, computerized-physician order entry and medical device alarms, among others. The National Quality Forum has endorsed 30 safe practices for healthcare settings, such as dispensing medications in unit-dose form, vaccinating healthcare workers against influenza, preventing mislabeling of radiographs and improving patients' informed consent.

The JCAHO's safety standards also serve as best practices. In 2003, the JCAHO instituted annual National Patient Safety Goals for accrediting hospitals. The 2004 goals include using at least two patient identifiers when taking blood, giving medications or blood products; conducting a "time out" before surgery to confirm correct patient, procedure and site; using a "read-back" between caregivers to verify verbal orders; using standard abbreviations, acronyms and symbols; removing concentrated electrolytes from patient care areas; limiting the number of drug concentrations available; marking surgical sites; complying with current Centers for Disease Control hand hygiene guidelines; and managing all unanticipated deaths or major permanent injuries from healthcare-acquired infection as a sentinel event. JCAHO is now tailoring its national goals to each of its non-hospital programs, including ambulatory care, assisted living, behavioral health, office-based surgery, home care, laboratory and long-term care.

In 2003, the American Academy of Orthopaedic Surgeons (AAOS) recommended best practices to eliminate wrong-site surgery in the U.S., including having the surgeon place his or her initials on the operation site using a permanent marking pen; operating through or adjacent to his or her initials; and having the surgical team take a "time-out" to communicate about the specific patient and procedure.

- **Designate a patient safety officer appropriate to each healthcare setting.**

Safety improvements do not take place without dedicated attention. For accredited institutions, JCAHO requires facilities to devote resources to safety programs, including designating a leader or interdisciplinary group to oversee and integrate an organization-wide safety program.[25] In general, hospitals and healthcare organizations are appointing

patient safety officers to work closely with interdisciplinary safety committees.

The American Hospital Association (AHA), in conjunction with the Health Research and Education Trust and the Institute for Safe Medication Practices, has created a job description for the patient safety officer. According to AHA's *Pathways for Medication Safety*, an organization's patient safety officer should oversee the patient safety program; coordinate the patient safety committee; oversee the management and use of medical error information, including reviewing internal error reports and using information from external reporting programs; investigate patient safety issues within the facility; facilitating root cause analysis; recommend and within the organization to improve safety; develop internal communication of patient safety information; design and implement educational presentations on safety; serve as a resource for clinical departments on patient safety issues; support and encourage error reporting throughout the organization by establishing a non-punitive error reporting system; and report to the governing body on healthcare errors, near-misses and dangerous conditions, as well as action to resolve them.

- **Protect any healthcare professional or employee who, in good faith, reports conditions or events that jeopardize patient safety.**

Every employee in the healthcare setting must feel secure and encouraged to report errors, as well as near-misses, to allow for investigation and correction of unsafe conditions.

The greatest obstacle lies in the so-called "culture of blame," in which healthcare staff, who report in good faith with hopes of improving safety, are punished either internally or externally with legal and professional repercussions. Adopting a "culture of safety" and separating "error" from guilt allows for the impartial analysis of accidents and the establishment of a meaningful incident reporting system.[26] Healthcare professionals and employees who in good faith report conditions or events that jeopardize patient safety should have protection, reserving blame and individual responsibility for incidents that are truly reckless and violate professional standards rather than arise from broken systems.[27] Culture change occurs when physicians, nurse, pharmacists, and other self-regulated professionals are encouraged and expected to report errors without fear of retribution.[28]

British researcher Reason lays out the framework to establish a "just culture" in which most participants share the belief that justice will prevail. He stresses that the "hang-them-all" judgment for persons who make mistakes is unacceptable, especially because all humans are fallible and those in highly technical and stressful industries like healthcare almost certainly will make mistakes. Establishing tests that evaluate intentions, actions, and consequences of errors will help distinguish between the best of people who can make the worst of errors and the worst of people who intentionally or recklessly harm patients.[29]

- **Promote evaluation and implementation of technological advances that enhance patient safety.**

The 2001 IOM report on healthcare quality, *Crossing the Quality Chasm*, called for transformation of the healthcare industry in six areas, including safety. This report articulated the central role health information technology must play in redesigning the healthcare system in the next decade.[30] Information technology can enhance consumers' health by making information available at their fingertips through the Internet and can improve clinical care.

Computerized physician order entry (CPOE) of medication, for example, is becoming an accepted goal for healthcare organizations, in part from a campaign by the Leapfrog Group, a coalition of more than 150 public and private organizations that provide healthcare benefits. The Leapfrog Group has recommended three practices specifically to reduce preventable mistakes in hospitals, including CPOE. Leapfrog wants physicians to enter hospital orders via a computer that includes prescribing-error prevention software and can alert physicians to at least half of common, serious prescribing errors.[31]

Bar coding can help reduce patient identification or medication errors by allowing a healthcare worker to verify medication administration at the bedside using hand-held scanners to record the patient's identity and information about the proper medication, eliminating errors involving the wrong patient, wrong drug, wrong route or wrong dosage. In 2003, the FDA announced requirements for drug manufacturers to add bar codes to drug labels. Research also has shown bar coding technology can reduce medication errors by up to 50 percent. In 2002, only 1.5 percent of hospitals were using machine-readable bar coding to verify all medications before administration to a patient.[32]

Impediments still block successful implementation of information technology for healthcare organizations and professionals: the cost of the software; hardware and personnel needed to support the technology; the acceptance of new technology by the healthcare workforce; the ease of using healthcare technology; the lack of national health information infrastructure; and health data standards that limit the ability of organizations and professionals to readily share data and information.

The benefit to patients, however, justifies a public organizational commitment to acquiring and using this technology to reduce adverse events and outcomes, whenever possible.

- **Establish an ongoing review of adequate availability of healthcare professionals and staff training**.

Healthcare organizations must acknowledge the relationship between workforce practices and patient safety, such as staffing patterns, adequate orientation and training and work design. Examples of recent changes in work practices to enhance patient safety include mandatory nurse-to-patient staffing levels for acute-care hospitals in California and changes to resident physician work schedules across the nation.

Contemporary literature suggests adequate nurse staffing results in safer patient care while understaffing is associated with increased length of stay, more infections contracted in hospitals and more pressure ulcers.[33] Because nurses account for the largest segment of the nation's healthcare workforce, IOM recently studied staffing levels and recommended such changes as involving direct patient personnel in setting staffing levels for each shift, providing slack within each shift to accommodate variations in patient volumes and illness acuity and allowing unit nursing staff to regulate workflow.[34]

Long work hours can pose a threat to patient safety because fatigue slows reaction time, decreases energy and judgment, and diminishes attention to detail. The IOM report called for state regulatory bodies to prohibit nursing staff from working longer than 12 hours a day and more than 60 hours per week.[35] A Missouri ad hoc committee on nursing staff, created by law in 2000,[36] recommended last year that the legislature prohibit hospitals from requiring nurses to work overtime and guarantee nurses who work more than 12 hours to have the option of at least 10 straight hours of uninterrupted off-duty time, but the General Assembly has not acted.

Similarly, in 2003, the Accreditation Council for Graduate Medical Education enforced new rules for workforce practices of resident physicians. These restrictions include a maximum 80-hour work week, adequate rest periods (10 hours between shifts); one day in seven free from patient care and in-house call no more than once every three nights.[37]

Work schedules that compromise patient safety make no more sense than punishing routines, which have been prohibited nationally, for long-haul truck drivers who must navigate busy interstates.

The commission recommends these protocols and processes as a starting point for Missouri healthcare organizations to ***publicly*** commit themselves to improving patient safety. The Missouri Center for Patient Safety's governing board and other advisers may refine these guidelines as necessary.

Creating Missouri's patient safety leadership and resources

Commission recommendation: A new private Missouri Center for Patient Safety should act as a leadership vehicle for patient safety improvements and be a resource for healthcare organizations, professionals and consumers.

The 1999 IOM report *To Err is Human* predicted that without a national focal point to beat the drum for patient safety, its goal of halving the rate of medical errors within five years would fall short. "Experience from other industries suggests that unless a (national) center is created or designated to keep attention focused on patient safety and enhance the base of knowledge and tools, meaningful progress is not likely," the report concluded.[38]

Five years later, no national center exists, and no one suggests that general medical error rates have dropped substantially, although areas of improvement have surfaced.

Without action on a national center, individual states with strong private-sector support moved to fill this void with at least 25 forming statewide public, private or partnership organizations that provide leadership vehicles to prevent medical errors.

Missouri joined that group when Gov. Bob Holden appointed this ad hoc Commission on Patient Safety in September 2003. All Missourians will benefit if a permanent body continues and expands the work begun by the commission.

The commission strongly endorses the establishment of a private Missouri Center for Patient Safety to act as an advocate for error reduction and assist in sharing information, identifying best practices, developing model curricula for professionals and disseminating consumer education materials.

The commission discovered that significant patient safety activities are occurring in Missouri, mainly in larger hospitals. This work, however, is fragmented and conducted in relative isolation. Facilities could make greater strides if healthcare organizations and professionals can easily share data, learn about and replicate existing models, gain greater visibility to educate the public and medical community and speak with a single voice to influence public policy.

Pending federal legislation also may create the immediate need for a designated body for patient safety functions in Missouri. As the commission completes its work, Congress is deliberating the Patient Safety and Quality Improvement Act (HR663 and S720), which has strong bipartisan support in both houses. If passed by Congress, the act would establish a voluntary system that allows healthcare organizations and professionals to report and analyze data on errors and their prevention. A patient safety organization in Missouri would collect the data identified in the act.

Structuring a state patient safety center

The commission studied other states' patient safety centers to identify what likely suits the unique needs of Missouri, its healthcare community and consumers.

The structure, mission statements and goals, membership, leadership, funding and other basic characteristics of state centers are almost as varied as the number of states that established them. Centers of this type hold the promise of encouraging the dialogue necessary to create a public/private paradigm for preventing harm, one that integrates the best elements of professional, consumer, purchaser, and institutional accountability with the most effective regulatory mechanisms,[39] but states will each approach patient safety initiatives differently unless Congress requires a single model.

The commission heard testimony on structure and design of centers that operate in several states, and this report outlines five possible approaches.

Massachusetts

Massachusetts has two agencies for patient safety activities that are designed to complement each others' work.

Established in 1998, the *Massachusetts Coalition for the Prevention of Medical Errors* preceded the IOM report. Through public and private education initiatives, it provides information to healthcare professionals and consumers on the causes of sentinel events and strategies for preventing medical errors.[40]

The coalition operates a website with information largely for healthcare professionals on medical error prevention while producing research publications and reports. Instead of data reporting on adverse events, the coalition focuses on dissemination of best practices, safety alerts and medication error information as well as promotion of medical safety projects. The membership includes hospitals, state professional healthcare associations, regulators, major consumer groups, the federal Centers for Medicare and Medicaid Services (CMS), JCAHO, insurers and healthcare professional educators. The coalition is funded by membership dues, including contributions from state agency members and other sources such as grants. The coalition operates from the Massachusetts Hospital Association.

Massachusetts in January 2004 also established the *Betsy Lehman Center*, named for the Boston Globe reporter whose death from a chemotherapy overdose literally ignited the past decade of national attention to medical errors. The center within the Massachusetts Department of Health relies on a three-year, $4.5 million federal grant for funding its study of medical errors' root causes. The program will collect and analyze data on medical errors, standardize patient safety programs, promote greater consumer involvement and research error reductions.[41]

Maryland

Maryland also coordinates patient safety through two agencies, which address system and quality improvement initiatives, error prevention, healthcare professional education and best practices identification, as well as state public mandatory and confidential voluntary reporting requirements.

The state legislature established the Maryland Patient Safety Coalition in 2001 — composed of 30 healthcare professionals, hospital associations, insurance companies and state regulators — to study a range of issues from whistle-blower protections, patient safety officer responsibilities, hospital risk management standards, surveys of hospitals on error prevention and quality improvements, medication errors and healthcare professional education.

The coalition's work led to the establishment of the *Maryland Patient Safety Center* in June 2004. The General Assembly ordered the Maryland Healthcare Commission and state health department to study a system to reduce patient safety problems, including accidents and medical errors. The Maryland commission selected the Maryland Hospital Association and Delmarva Foundation (Maryland's Medicare quality improvement organization) to operate the new center. The hospital association and Delmarva will provide funding for the center during its first three years of operation, supplemented by private donations.[42]

Maryland in 2004 will require hospitals to report sentinel events that cause patient death or harm. Maryland also established a voluntary reporting system for all incidents, including less serious ones and situations that could have resulted in patient harm. The *Maryland Department of Health and Mental Hygiene* will analyze the mandated error reports while the Maryland Patient Safety Center will address voluntarily reported information.

Florida

In June 2004 Governor Jeb Bush signed legislation to create the *Florida Patient Safety Corporation*, which will collect and analyze data, study near-misses, promote best practices, encourage development of electronic records and operate a library of evidence-based medicine.[43] Licensed facilities are required to designate patient safety officers and committees to recommend improvements.

The agency will operate as a private, not-for-profit organization run by a 15-member board, appointed by the governor, that includes representatives from providers, a medical school dean, insurers and the AARP. The legislature provided its startup funding of $650,000, but the corporation is designed to seek private funding. The Florida Agency for Healthcare Administration within the Department of Health will handle the state contract with the coalition and provide logistical support.

State medical educators also are scheduled to report to the governor in August 2004 on the state's implementation of patient safety activities and reporting systems. Florida already requires reporting of sentinel events to the state.

Georgia

The Georgia Hospital Association founded the *Partnership for Health and Accountability* in January 2000 with physicians, state health officials, legislators and businesses as other stakeholders. Most partnership activities focus on reduction of medical errors in hospitals, emphasize a blame-free environment to encourage reporting of medical errors, promote education on best practices, issue consumer advisories and alerts and publish research.

Since its inception, the partnership has garnered national attention for its innovation and success in reducing medical errors in hospitals.[44] Georgia hospitals, working with the partnership, have shown improvements on specific health indicators at a rate faster than the CMS national average quality improvement rate. They also document significant improvements in moving participating hospitals into the "culture of safety" on error reporting, with up to a 30 percent increase in some areas from 2001 to 2002.[45]

The *Georgia Partnership for Health and Accountability* receives funding through multiple private sources. The Georgia Hospital Association provides support, as do private businesses and grants. The partnership receives no funding from the state of Georgia.

Wisconsin

The *Wisconsin Patient Safety Institute* was launched in 2001 by 15 founding organizations, including the state's Medicare quality improvement organization, professional healthcare associations, the public school employee trust fund and a medical school.[46]

The institute is a private, not-for-profit organization that supports translating research into the clinical setting, closing the gap between what *can* be done and what *is* done by identifying best practices and patient safety research, and providing a forum for patient safety advocacy. The institute has completed three significant projects documenting as much as a 39 percent increase in medication safety activities in Wisconsin hospitals from 2000 to 2002.

The institute is financed by its founding organizations as well as other private sources, but not the state. The board of directors includes membership from private business, associations, consumers, legislators and state agencies involved in healthcare.

The Missouri proposal

To assist healthcare organizations, professionals and consumers, the commission proposes that the Missouri Center for Patient Safety, at a minimum, adopt a mission to:

- **Provide leadership for improvements in patient safety.**
- **Develop and promote minimum patient safety standards for healthcare organizations and professionals.**

- **Establish a "consumer coalition" to make the patient a more active, better-informed member of the treatment team.**
- **Act as a research institute for the collection, analysis and sharing of patient safety data.**
- **Promote the use of best practices in all healthcare settings.**
- **Assist healthcare organizations in developing counseling resources and support groups for patients and facilities affected by adverse events and outcomes.**
- **Develop and promote undergraduate, graduate and continuing education curricula on patient safety through an "education coalition."**
- **Assist outpatient settings, such as smaller physician practices, in developing patient safety models that adapt to their size.**
- **Develop and implement award/ recognition programs for outstanding patient safety achievements.**
- **Adopt a common terminology and data sets for patient safety in Missouri.**
- **Act as the state patient safety organization if federal legislation passes.**

The commission recommends that the patient safety center operate with these characteristics:

- A private, not-for-profit corporation.
- A governing board with representatives of diverse public and private organizations. A freestanding organization not associated with a state agency or a particular private interest group.
- Committed leadership from key healthcare organizations.
- A partner with state agencies on ongoing and special projects.

The healthcare community, motivated by common interest in improving patient safety and healthcare quality, is capable of building such a Missouri Center for Patient Safety. Many questions remain, including identification of the members; their role, the leadership and startup and ongoing funding.

MissouriPRO (the state's Medicare quality improvement organization), Missouri Hospital Association, Missouri State Medical Association, the Missouri Association of Osteopathic Physicians and Surgeons, Missouri Academy of Family Physicians, other professional societies and the Missouri Association of Health Plans all have vested interests in the success of such a center and should act as major stakeholders.

Balanced leadership and management will sustain member interest and benefits, foster links between the center and constituencies, assist in funding and promote the visibility of the center. Domination by a major stakeholder, as in some state models, likely would undermine the acceptance and credibility of the organization. A critical element in the center's success lies in identifying the right blend of stakeholders that bring together the talents and resources necessary to achieve the center's goals.

Other membership could include:

- Healthcare professional educators.
- Consumers/purchasing groups/unions.
- Hospitals/medical groups.
- Professional liability insurers.
- National and state healthcare organizations.
- Health insurance plans.
- Other professional/provider associations.
- Long-term and home care services.
- Department of Health and Senior Services.
- State licensing boards and insurance regulators.
- Attorney general.
- Legislators.

States have taken myriad approaches to another critical question – how to fund a patient safety center. They often do not look to government as the sole source of funding. A few, like Georgia do not turn to government for funding at all. Each funding source comes with positives and negatives. Among the options are membership dues for organizations, service fees, corporate/association sponsorships and grants besides government and corporate contracts for specific projects, government-imposed fees and appropriations, including tobacco settlement funds.[47]

If Congress enacts legislation that makes each state responsible for voluntary data reporting, federal funds could become available.

Research, reporting and analysis

Follow-up congressional action to the 1999 IOM report likely has been delayed because one of its four principal recommendations called for mandatory reporting of adverse events that cause death or serious harm. While the report provided for confidential voluntary reporting of less serious events and conditions, the mandatory data would not have been protected from public disclosure.

Essentially all professional organizations opposed congressional adoption of the IOM recommendations unless mandatory reporting elements were removed. All have cited the possibility of increased malpractice litigation if such information becomes publicly available, although others also have expressed reservations about likely workload. Those organizations now support HR663 and S720 because the bills contain confidentiality provisions with only *voluntarily* reported data and no mandates.

Missouri has had virtually no history of provider reporting in the patient safety area. Only self-insured healthcare organizations must report malpractice claims filed and closed; insurers file the malpractice claim reports on behalf of the healthcare organizations they insure. Hospitals and ambulatory surgical centers must report final disciplinary action against licensed healthcare professionals, but nursing homes, group practices and other organizations are exempt. This year, the General Assembly passed and Gov. Holden signed SB 1279, a new infection control act that requires hospitals, ambulatory surgical centers and some facilities other than physician practices to report infections contracted within facilities.

About 21 states, including Kansas, have mandatory reporting of adverse events.[48] Most existing state systems require reporting of events that result in death or major permanent harm. Few encourage the reporting of near-miss events. While voluntary reporting systems are designed for learning and safety improvement, mandatory reporting systems aim to hold providers accountable. In general, state mandatory reporting systems are operated by regulatory bodies that investigate reports, require corrective plans and issue penalties. The information often is open to public scrutiny.

Healthcare professionals, organizations and professional healthcare associations have their own justifiable concerns about reporting mandates. Legislators, healthcare associations and regulators need to work closely to determine what information, if collected and analyzed, will help prevent future medical errors.

The commission makes no recommendation on whether Missouri should *require* reporting of adverse events. The board of the new center can address issues related to required reporting as information sharing develops.

However, the commission strongly recommends that the Missouri Center for Patient Safety establish a system for voluntary reporting of adverse events that is essential to improving patient safety in this state. Besides adverse events, reporting should include their outcomes, near-misses and solutions developed for patient safety problems.

In Missouri, knowledge of adverse events and subsequent corrective actions almost always remains within the walls of the healthcare organizations where they occur. Information sharing among healthcare organizations and professionals on the conditions that breed errors and how to avoid them is the exception rather than the rule. The status quo leaves smaller organizations and their patients at a particular disadvantage; these facilities may not have the volume of procedures needed to identify problem areas – until catastrophic mishaps and patient injuries happen that they are less equipped to manage.

Voluntary reporting on adverse events and solutions will allow the Missouri Center for Patient Safety to begin to identify likely problem areas and proven best practices for use by all the state's healthcare organizations and professionals to prevent injuries. What works well in one small group practice, for example, likely can serve as a model for others.

The advent of voluntary reporting of adverse events will require legislation to protect confidentiality and encourage reporting. Even the broadest reading of Missouri's peer review statutes will not provide immunity, privilege and confidentiality for information that is voluntarily reported outside the healthcare organization.

Adopting a common patient safety language

If the federal legislation passes, the center could coordinate research and other projects with national and other states' efforts as Missouri's designated patient safety organization.

Even without congressional action, Missouri needs a lead organization to work with private agencies and other states on common problems. For example – in what seems like a housekeeping chore, but has become a major headache – no common set of data elements and terminology on safety exists nationally or within Missouri. Each state, federal agency or healthcare organization develops its own lexicon and definitions for information. For example, some state reporting systems use the term "occurrence;" others use the term "incident," while the IOM report used the term "event." Even this report needed to include its own glossary. This lack of a standardized language limits the sharing and comparison of information about adverse events and near-misses, their root causes and solutions throughout the healthcare industry. Work is under way nationally to develop a common vocabulary for reporting, research and analysis on patient safety.[49] The IOM, the National Quality Forum, the AHRQ and JCAHO are all working to develop a patient safety lexicon.

Once in place, the center should adopt this standard lexicon for Missouri's healthcare organizations to use in patient safety reporting, research and analysis and promote its use.

Empowering the consumer to improve patient safety

Commission recommendation: A consumer coalition in the Missouri Center for Patient Safety should help empower patients to play a central role in their own healthcare and take precautions for their well-being in healthcare settings.

Consumers are insightful about the problems in modern healthcare settings that contribute to errors, frustrated by communication problems with their healthcare teams and supportive of steps – many suggested in this report – to improve healthcare and prevent errors.

A research team from the Harvard School of Public Health and the Kaiser Family Foundation in 2002 surveyed more than 1,200 American adults and found:

- Forty-two percent had experienced medical errors in care for themselves or family members. Ten percent of the public had relatives who had died from medical errors. Only 6 percent, though, had been involved in malpractice cases.
- Half the respondents believed such errors occurred very or somewhat often when consulting a healthcare professional.
- 72 percent – the highest ranking – said insufficient time with physicians was a very important cause of preventable medical errors, compared to a response of only 37 percent from physicians themselves, surveyed separately. The consumers also identified fatigue and stress among healthcare workers (70 percent), failure by healthcare professionals to communicate or work with each other (67 percent) and nurse understaffing as other important causes — all issues addressed in the proposed Missouri Center for Public Safety's agenda.
- Not surprisingly, the public believed that more physician-patient contact would provide a "very effective" solution for reducing errors. But consumers also strongly supported requiring hospitals to develop error-prevention systems (74 percent), mandatory (71 percent) and voluntary (62 percent) reporting of errors to state agencies and better training of healthcare professionals (73 percent). Again, 62 percent believed that the public should have access to error reporting results.
- 89 percent believed that rules should require physicians to inform them when errors had been made, compared to 77 percent of doctors in a separate survey.[50]

Taken as a whole, the results speak to consumers' need for more information – both about their conditions and treatment plans and about the facility where they are receiving care. The findings are consistent with dozens of other studies that show communication breakdowns and deficits commonly occur with patients, make treatment less effective and contribute to the incidence of malpractice actions.

Ideally, patients want to obtain treatment information from their physician, but time pressures and workloads in modern medical settings undermine those expectations.

The commission recommends that the Missouri Center for Patient Safety establish a *consumer coalition* that would help patients become more active, better-informed members of their treatment teams who can help prevent errors in their own care. This coalition should include not only patients and advocacy groups, but health-care purchasers — principally employers and unions — that have a vested interested in the quality and safety of care provided to employees and their families.

The commission concluded **the consumer coalition – with the center's full support — should**:

- **Conduct consumer research to better document patient needs for information and concerns about safety.**
- **Develop easily accessible, reliable educational materials – especially interactive and Internet-based tools** – for consumers and for physicians and other healthcare professionals who are hard pressed to meet their needs.
- **Disseminate information on how consumers can detect and prevent conditions that endanger their safety.** For example, the center can issue "consumer alerts" on disturbing trends in errors identified in its voluntary reporting system and advise consumers on steps they can take to avoid harm, such as identifying providers that use best their practices.
- **Work to make more information available to patients about choices in healthcare professionals, their safety records and quality of care.** Information in Missouri — and across the country — is not highly developed on quality and safety issues. Missouri shortly will begin publicly reporting rates for infections contracted within hospitals and other facilities, the Missouri Hospital Association has begun a voluntary reporting program on quality measures, and some private health plans make performance information available to their members. But consumers are still handicapped by a paucity of relevant information for choosing healthcare organizations and professionals and participating in their own treatment plans.
- **Support other consumer healthcare advocacy organizations and complaint investigation activities of state agencies.**
- **Speak forcefully for patients' interests within the Missouri Center for Patient Safety.**

The commission also recommended that all healthcare organizations make patient advocates available who can answer questions and steer consumers to reliable information about their health conditions. Such advocates can provide critical assistance to patients who are concerned about hospital procedures and issues of safety and quality.

Building a legal framework for patient safety

Commission recommendation: Missouri should provide statutory protection for patient safety activities to encourage healthcare organizations and professionals to voluntarily report information and participate in the peer review/quality improvement process.

- On a locked mental ward, a patient apparently leans against a screen and falls from the second story. The hospital's patient safety officer assembles a team to study what occurred, including three licensed nurses, a licensed psychiatrist, a medical resident, a licensed social worker and the patient safety officer. The team wants to include a maintenance department staff member and an architect in discussions on how to prevent such falls from occurring. The hospital's attorney cautions against including the maintenance employee and architect in any deliberations – as well as the patient safety officer and medical resident.

- Physicians in an ambulatory surgical center conduct an investigation after a serious medication overdose permanently injured a patient. They want to discuss the incident with physicians and pharmacists from another facility to see if common patterns emerge, but cannot if they want to guarantee no legal entanglements.

- Respiratory therapy equipment repeatedly fails, causing complications for several patients with breathing problems. The hospital's patient safety committee learns that it cannot work with any of the hospital's licensed respiratory therapists – other than as formal witnesses.

In these cases today, Missouri healthcare organizations are in legal limbo.

They face potentially unacceptable risks if they investigate adverse events, including deaths, and take steps to prevent errors from recurring. Some hospitals, clinics and practices nevertheless are taking those risks to improve patient safety while an unknown number of others are reluctant to proceed because of the chilling effect of legal liability.

Healthcare administrators now have few choices but to seek legal haven for patient safety activities under Missouri's "peer review" statute, which originally was designed to protect physicians from civil liability when they participated in hospital disciplinary proceedings against medical colleagues. Missouri's current legal framework for peer review dates from 1985, but the state's courts have never ruled in a case simply involving the status of patient safety committees and officers and their investigations of adverse events.

'Culture of blame' v. 'culture of safety'

The Missouri Commission on Patient Safety recommended that all healthcare organizations adopt internal adverse event reporting systems, analyze the root causes and devise solutions to prevent errors from happening again. For such systems to work effectively, healthcare professionals, facility staff, patients and others must feel free to report and explore events that harm or could have harmed patients.

Such an atmosphere represents a decided shift from the longtime "culture of blame" and individual responsibility long associated with medicine, its licensing standards and discipline. When mishaps occur in medical settings, the emphasis quickly can become finding "who" committed the error. Identifying "who" can lead to curtailment or loss of privileges in the hospital and possible licensing action by state boards. Identifying "who" is pivotal in medical malpractice actions because, otherwise, no one is negligent and responsible for payment of the patient's damages. Such an orientation – fraught with the perils and expense of legal action, loss of reputation and other negatives – naturally discourages the acknowledgment, reporting and solution of adverse outcomes and near-misses in patient care.

Less well understood, at least by the general public, are the dangers of internal reprisal if healthcare staff report to facility administrators – not to mention

patients and families – that an error occurred in treatment.

Following similar recognition in aviation, nuclear power and industrial settings, the medical community is reaching consensus to build a "culture of safety," which has four main components:

- Acknowledgement of the high-risk, error-prone nature of medical practice.
- Creation of a "just" environment that allows, indeed encourages, healthcare professionals to report errors or near-misses without punishment.
- An expectation that all staff will work together to resolve the problem.
- The organization's willingness to solve the problems identified.

Making this transformation in Missouri lacks an essential element: legal protections. Simply put, hospitals and other institutions are less likely to establish internal reporting programs, and staff will have greater qualms about reporting errors, thoroughly investigating their causes and preventing recurrences if they potentially are documenting a medical malpractice case or leaving themselves vulnerable to reprisal.

More than 5.6 million patients in Missouri have much at stake on how the lines are redrawn to protect modern patient safety analyses. They benefit if this new culture dramatically reduces an error rate intolerable in other industries. If the protections are worded too broadly, however, victims of negligence, recklessness or incompetence – which do exist — could face even greater obstacles in obtaining adequate compensation for their injuries, lost income and future medical costs.

The peer review statute

Healthcare organizations and professionals committed to improving patient safety must rely on the makeshift legal protection of Missouri's 31 years of "peer review" statutes and case law that have their very roots in the "culture of blame" and do not easily accommodate immunity, privilege and confidentiality for broader patient safety investigations.

Section 537.035, RSMo, originally was conceived to shield hospital peer review committees, professional colleagues, governing boards, executives and witnesses when investigating incidents and disciplining physicians and other licensed healthcare professionals who violated standards.

The statute first was enacted in 1973 to protect against civil liability in lawsuits filed by the professionals who were investigated. The law initially protected only physicians, dentists, podiatrists and optometrists.

The Missouri Supreme Court underscored the narrow limits of this statute in 1984 when it ruled in *Chandra v. Sprinkle* that "no peer review privilege exists under Missouri law for factual statements."[51] Consequently all documents in the peer review process were open to discovery in legal proceedings, although protected professionals were not subject to damages for good faith actions.

The General Assembly responded immediately in 1985 by revising Section 537.035 RSMo to provide for civil *immunity* from damages for those persons involved in the peer review process as well as *privilege* that shields peer review committee records from discovery and *confidentiality* that prohibits the questioning of peer review committee participants about its proceedings.

But the legislature also:

- Broadened the peer review committee's jurisdiction from violations of professional standards to the responsibility "to evaluate, maintain and monitor the quality and utilization of healthcare services." Those who try to squeeze patient safety investigations under the peer review umbrella generally look to this language; that view was strengthened in the 1997 case of Lester E. Cox Medical Centers v. Darnold, which extended privilege for a "quality assurance, quality assessment and/or quality management report" of the committee.[52]

- Limited the privilege to peer review records that concerned "the healthcare provided any patient." This language, combined with subsequent court rulings, suggested that peer review records on hospital conditions – not relating to specific care for a patient – are open to discovery and lack confidentiality.
- Restricted committee membership to specific licensed professionals, shareholders of healthcare corporations and partners in healthcare partnerships. Although other hospital staff may appear as witnesses, they must leave the room during any deliberations, or legal protections are lost.

The law does not shield original medical records or prohibit testimony on occurrences outside committee proceedings. Otherwise, legitimate malpractice victims might never be able to document their cases or depose any participants. None of the restrictions on access to peer review records and participants applies to state licensing boards.

The law includes at least two flaws:

- The peer review committees' rosters must include only specific licensed healthcare professionals — physicians, dentists, podiatrists, optometrists, chiropractors, psychologists, nurses, social workers, counselors, mental health professionals and, in some cases, owners of a healthcare organization. Not all state-licensed professionals are covered. Investigating and improving patient safety, may need to include a potentially broad spectrum of personnel, such as risk managers, patient safety specialists, physician assistants, nurse practitioners and anesthetists, licensed respiratory therapists, engineering staff and housekeeping personnel that are now barred from membership on these committees. Kansas, for example, has expanded its protections to include risk managers and other staff. Illinois has provided a much broader area of privilege and confidentiality under its Medical Studies Act.
- Because they are not committee members, non-licensed and some licensed staff are not allowed to participate in decision-making on remedial steps, or the entire process could lose legal protection.

Other existing legal protections

A scattering of evidentiary rules may provide some protection of patient safety information from disclosure.

Missouri is among the 49 states adopting the rule that a plaintiff cannot submit **remedial action** as proof that negligent medical care occurred. The rule encourages healthcare organizations and professionals to improve practices without fear that it admits prior practices were substandard or negligent.

Some healthcare organizations in Missouri invite their attorneys to attend patient safety meetings in Missouri so that the proceedings are subject to **attorney-client privilege**. While this privilege is nearly absolute, the cost further acts as a disincentive for patient safety activities.

The doctrine of **attorney work product** also may provide some protection for patient safety activities – but only if they are performed "in anticipation of litigation," which is a standard that is difficult to meet.

Removing legal barriers to patient safety

As long as uncertainty exists about the legal status of root cause analysis and other patient safety activities, many conservative healthcare organizations will not embrace the commission's recommendations – and the national consensus – on how to reduce medical errors and save lives. The General Assembly has an obligation to the public to provide clear legal standing – even if it isn't perfect – for all institutions to seriously address error prevention.

The commission decided not to submit draft language on statutory changes, but recommended that the legislature:

- **Create protections for information shared among healthcare organizations and professionals that is designed solely for improving patient safety and healthcare delivery systems.** The General Assembly may choose to expand peer review protections to cover patient safety or create new statutes that relate only to internal patient safety activities. Creating separate statutes would leave intact current case law on peer review, meager as it is, and remove patient safety from the disciplinary process, although the two functions will often overlap.
- **Expand the qualifications of members on peer review/patient safety committees to allow full participation by licensed healthcare professionals not listed in the statute, non-licensed professionals like risk managers and other employees who play key roles in safety improvements.**
- **Eliminate cumbersome requirements for appointing peer review committees.**
- **Protect patient safety data, documents and information reported to the Missouri Center for Patient Safety from use in civil, judicial and administrative proceedings.**
- **Protect the job status of healthcare professionals and organization employees from reprisal for reporting errors internally and to the Missouri Center for Patient Safety.**

Incorporating patient safety into Missouri's professional healthcare education

Commission recommendation: Missouri healthcare schools and licensing agencies should establish curricula of key patient safety concepts for the primary training and continuing education of professionals.

To build a "culture of safety" that reduces medical errors, Missouri must begin at the beginning – the pre-licensing education of tomorrow's physicians, nurses and allied health professionals and the re-education of considerably more than 100,000 already-licensed caregivers.

The 1999 IOM report only broadly addressed the issue of professional education, calling for "colleges of medicine, nursing, pharmacy, healthcare administration and their related associations…(to) build more instruction into their curriculum on patient safety and its relationship to quality improvement."[53] Two years later, the IOM's *Crossing the Quality Chasm* recommended "restructuring clinical education" – at the undergraduate, graduate and continuing education levels – "to be consistent with the principles of the 21st century healthcare system," including systems-based approaches to care.

With only five years passing since *To Err is Human* raised American consciousness about the pervasiveness of errors in high-risk medicine and the need for reforms, patient safety in the professional education curricula remains in its infancy.

The commission found:

- **No lead agency – a "champion of patient safety" – exists to promote the need for educational improvements at all levels of care in Missouri.** Patient safety must compete with the explosion of medical knowledge and clinical innovations for limited places at the table of professional education. Missouri patients need a strong voice to represent their interests in ensuring that educational programs emphasize safety.
- **Patient safety, in its modern context, is not yet a standard component of professional healthcare schools' curricula**.
- **Patient safety is not a mandatory element for Missouri professions whose license renewals depend upon continuing education**.
- **Professional schools need assistance and funding for re-tooling curricula and teaching resources.** Besides technical assistance on curriculum development, many faculty members need access to further education in these areas. Institutions indicated students' experiences are limited by the philosophy of affiliated teaching hospitals and whether they embraced patient safety concepts.
- **Educators need to help develop the interdisciplinary, collegial framework needed for error analysis and prevention.** Healthcare continues to struggle with a traditional, hierarchical structure often at odds with the culture of safety, and more collaborative education needs to take place with nursing, medical and allied health students to overcome these barriers.

The commission recommends formation of a broad-based education coalition within the Missouri Center for Patient Safety to act as that "champion" – providing leadership on the issue, helping assess the needs of the schools and their students, providing technical assistance on curriculum design, working with accreditation agencies on curriculum standards, pressing for minimum continuing education requirements for licensees and, in particular, stressing the need for better communication training for healthcare professionals.

The commission also looks to this coalition to provide leadership in improving communications of healthcare professionals with patients and each other as well as the rapidly growing challenges of bridging the communications gap with Missouri's minority communities.

Curriculum development

- **The Missouri Center for Patient Safety's educational coalition should work with accreditation agencies responsible for establishing healthcare professionals' education requirements to incorporate key patient safety concepts into the curricula.**

The six medical schools in Missouri look to the Accrediting Council for Graduate Medical Education (ACGME) or the American Osteopathic Association's accrediting arm for approval of curricula and training. ACGME in 1999 overhauled its curriculum guidelines to stress six "core competencies" – patient care, medical knowledge, practice-based learning and improvement, communication skills, professionalism and systems-based practice. Although patient safety and the "culture of safety" were not addressed specifically – the IOM report had just been released – such elements are scattered among these competencies, particularly for systems-based practice and learning/ improvement.

As one research team summarized this year: "Patient safety issues are not a priority in undergraduate curricula"[54] for medical, nursing and other professional schools. On the heels of the IOM report, an August 2001 report by the Association of American Medical Colleges (AAMC) painted a stark picture of education on patient safety issues, citing "concerns" that "medical school graduates are ill-prepared to address the system shortcomings that put patients at risk in the first place. These system shortcomings result in the overuse, underuse, and misuse of medical care, preventable errors and even death."[55] Calling for a "culture change," AAMC noted that the medical education community had worked previously to "insulate" students and residents from "public accountability," which had gravitated against "systemic study of errors and quality."[56]

The Missouri schools generally indicated that they have only recently or are still implementing curriculum changes on modern patient safety concepts, as opposed to traditional risk management issues on legal liability.

The Missouri Board of Nursing, the state-licensing agency, accredits undergraduate education programs for registered and licensed practical nurses at 92 schools in Missouri. The board indicated that no specific requirements exist for patient safety education in these programs, although all have content on legal issues that includes general safety and risk management issues.

The state's minimum standards for nursing programs are written broadly as are the criteria by other bodies such as the National League for Nursing Accrediting Commission (NLNAC) and the Commission for Collegiate Nursing Education (CCNE).

The commission recommends that the Missouri Center for Patient Safety and its education coalition:

- Help develop standardized core education modules that target healthcare professional students, based on the proven elements like root cause analysis for improving patient safety.
- Promote the development of interdisciplinary training. For example, the University of Missouri-Columbia offers a course that places nursing students in their final year, health administration graduate students in their final year and second-year medical students in small groups to work on root cause analysis projects. The course, now in its second year, includes lectures on the IOM report and the epidemiology of errors as well as role-playing on the disclosure of errors to patients. Once fostered among young students in training, relationships marked by collaboration and respect are easier to maintain in the healthcare setting.
- Act as a clearinghouse to collect and disseminate patient safety educational materials.

Many promising projects are coming on-line across the country. Case Western Reserve University, for example, has gained national attention for its emphasis on medical students' application of quality improvement knowledge in clinical settings. A Florida study group, after interviewing national authorities in

the field, cited New York Medical Center, the University of Washington and the University of Minnesota for their work on patient safety education. These still represented wee steps: the Minnesota project involved an interdisciplinary team designing a combined ethics and patient safety course as a requirement before students were admitted to medical, nursing and other healthcare schools.

Curriculum design is not limited to academia. In Massachusetts – a hotbed of patient safety activity – the state medical society last year completed design of its three-module curriculum on medical error scenarios, root cause analysis and medication safety. A leader in the patient safety field – the Veterans Administration National Center for Patient Safety – has developed and tested curriculum for medical residents and students. Numerous professional societies are involved in some stage of curriculum design, in part because the IOM in 1999 specifically called on them to "develop a curriculum on patient safety and encourage its adoption into training and certification standards"[57] for physicians and other professionals.

Developments includes considerable work on using simulators – rather than live patients – to make resident education itself safer, at least for its subjects, as prospective physicians-in-training gradually assume more responsibility for care. The 1999 IOM report urged healthcare organizations and teaching institutions to help develop and use simulators for training novices, problem solving and crisis management, particularly when new, potentially hazardous equipment and procedures were introduced.[58]

Continuing education

- **The commission recommends that the education coalition promote patient safety competency of healthcare professionals through continuing education activities.**

Healthcare professionals, more than most others, require lifelong learning so that providers select from the most current arsenal of treatment approaches, medications and technologies. Missouri, like virtually all states, requires physicians, nurses and others to complete continuing education and remain abreast of new developments.

Missouri, however, does not mandate that licensed healthcare professionals complete any patient safety courses as part of their continuing education requirements for license renewal. The Missouri Board of Registration for the Healing Arts, Board of Nursing and Board of Pharmacy do not mandate patient safety continuing education requirements, nor are they allowed by law to do so.

If public officials and the healthcare community determine that Missouri should adopt a "culture of safety" and all that portends, they must recognize that 14,000 in-state physicians, 86,000 nurses and thousands of other licensed healthcare professionals have little acquaintance with system-based practice and little likelihood of embracing it without mandatory continuing education. Florida and other states have done so.

Such continuing education need not merely provide theoretical background that detracts from a professional's time. Using case study reviews that incorporate patient safety techniques for continuing education, a 13-member Pennsylvania radiology group reduced its error rate on stroke diagnosis from 18 percent to 1 percent while cutting its inconclusive readings on breast cancer exams from 14 percent to 6 percent, saving 1,600 women the need for second exams.[59]

Communications – a key to avoiding poor outcomes, litigation

- **The commission recommends that the education coalition promote improved communication among healthcare professionals and with patients at all levels of healthcare delivery.**

Ineffective communication across healthcare settings, among healthcare professionals and with healthcare consumers increases exponentially the risk of

misunderstanding, noncompliance with treatment plans, poor outcomes and error. ACGME has included communications skills for students among its core competencies, but field surveys indicate improving communications represents an enormous challenge for the entire healthcare community.

Significant portions of the general public share concerns about the quality of communication between physicians and patients. The 2002 Commonwealth Fund International Health Policy Survey of Sicker Adults found in the area of patient-physician communication that American patients reported that their regular doctor or health professional does not:

- Make clear the specific goals for treatment 20%
- Help understand what needs to be done for health 14%
- Ask for ideas and opinions about treatment and care 47%[60]

These figures rise markedly for minority Americans. In the 2002 Harvard-Kaiser survey of 1,200 adults, 72 percent said inadequate time with physicians was a major cause of medical errors – a proxy for communications problems.[61]

Beyond the risks to quality of care, virtually no one in the healthcare community today contests the conclusion that poor communications result in an increased rate of medical malpractice litigation and expense. Only 2 to 4 percent of patients who actually suffer from medical error ever file a malpractice claim, but poor communications swell that rate for a small group of professionals – repeatedly. When physicians are not equipped to manage difficult situations, anger and misunderstandings fuel litigation by patients who suffer poor outcomes even when no medical error occurred.

On February 4, 2004, the commission heard testimony from Dr. Gerald Hickson, the associate dean of clinical affairs at Vanderbilt University, who is regarded among the nation's leading authorities and researchers on physician communication skills and their effect on outcomes and litigation.

Hickson cited numerous studies that, viewed as a whole, suggest poor patient communications are a powerful motivator of malpractice actions. For example, one report found only 3 to 8 percent of Florida physicians were responsible for 75 to 85 percent of all claims payments. The same pattern surfaced for all specialties identified, no matter the inherent risk of their practices.[62] Another study identified more than 1,500 Florida obstetricians by their level of risk based on claims history. Professionals' blind chart reviews in these cases found no differences among no-, moderate- and high-risk physicians on the quality of documentation, use of tests, medical episodes with marginal or inadequate care, or in the subjective judgment of the physician-reviewers.[63]. But the researchers found that physicians with a high-risk of malpractice actions had been the subjects of twice as many complaints as no-claim doctors, with poor communications the most commonly cited problem.[64]

One of Hickson's studies involved 127 Florida families whose children had suffered permanent neurodevelopmental injury or death. When interviewed about their decisions to file a lawsuit, more than 75 percent cited reasons other than the possible monetary award. Fully one-third were advised to do so by others, mainly physicians. One of every five proceeded because they believed the physician would only divulge the truth on the witness stand.

All in the healthcare community suffer when the communication deficits of a few inflate malpractice costs, disrupt work routines and damage the public perception of healthcare professionals. These circumstances represent a "preventable error" that the healthcare community, educators and even licensing agencies can help remedy. Such poor communication also has a direct effect on patient safety if it creates obstacles to implementing the commission's recommendation that all healthcare organizations and professionals disclose errors to patients and their families.

Communication problems grow when healthcare professionals deal with minority communities, which represent a rapidly growing challenge; their share of the U.S. population is expected to increase from 27 percent today to almost half by mid-century.

While a disturbingly low 57 percent of those surveyed for a 2001 Commonwealth Fund study found it easy to understand materials from their doctors' offices, including critical prescription instructions, the numbers dropped to 45 percent for Hispanic and 44 percent for Asian-American patients. One-third of Hispanics, 27 percent of Asians and 23 percent of African-Americans reported that their doctor didn't listen to what they said, they didn't understand what the doctor said or they left the office with unanswered questions.[65]

Educators also can work with students and professionals to help reduce the errors related to miscommunication *among* professionals. In the 2002 Harvard-Kaiser survey of 1,200 adults, two-thirds said the failure of healthcare professionals to communicate and work together as a team was a major cause of medical errors.[66] Among the difficulties to overcome here is encouraging effective interdisciplinary teamwork when professional relations between physicians and nurses have been historically strained.

Communications breakdowns – often when humans try to talk or scribble rather than relying on more reliable and accurate technology – have an undeniable impact on error rates and patient outcomes, such as medication errors that account for perhaps 10 percent of adverse events.

The 2004 IOM report *Patient Safety: Achieving a New Standard for Care* reiterated the need to develop a computerized patient information system, which includes electronic prescribing.[67] The FDA has directed the use of bar-code label requirements for pharmaceuticals that can automatically detect mistakes in prescribing and dosages — if facilities have the proper computer systems. The FDA estimates that the bar code rule, once implemented, will result in more than 500,000 fewer adverse events over the next 20 years.[68]

Ensuring safe levels of care by Missouri's licensed healthcare professionals

Commission recommendation: Legislators and elected officials should work with healthcare organizations, professionals and regulatory agencies to evaluate and address effective regulation of licensees in the interest of patient safety.

The Missouri Commission on Patient Safety's conclusions on the need to abandon the "culture of blame" in Missouri healthcare do not mean individual licensed professionals or their organizations are no longer accountable for their actions.

Physicians, nurses and other licensees who are reckless, incompetent, impaired, negligent or abusive need at least mandatory rehabilitation, if not licensing action to protect the public. By all known measures, such professionals are a decided minority of licensees, but account for the bulk of patient complaints, malpractice actions and hospital disciplinary actions.

A consumer group's study of the National Practitioner Data Bank, which compiles reports on malpractice actions, indicated that 5.1 percent of American doctors accounted for 54.2 percent of paid claims from 1990 to 2002. Yet less than 8 percent of physicians with multiple claims paid were disciplined by state licensing boards.[69] Critics have contested interpretations of that study, but the Missouri Department of Insurance, which by law should receive reports on all malpractice claims filed and closed in the state, also found that a small percentage of physicians and other individual licensees with multiple paid claims accounted for a disproportionate share of malpractice costs from 1990 to 2002.[70]

Multiple claims, even when they result in payments, do not necessarily indicate that these healthcare professionals are unsafe practitioners. Landmark studies by Dr. Gerald Hickson of Vanderbilt University, who addressed the commission, indicate that some physicians have such poor communications skills – "bedside manners" – that they attract a disproportionate share of patient complaints and malpractice claims.[71] Other physicians may practice high-risk specialties more prone to litigation, although research indicates that even in these areas, a small number of physicians accounted for the bulk of patient dissatisfaction.[72]

To date, Congress, the General Assembly, insurers and healthcare organizations generally have not provided access to quality and safety information that would help Missouri consumers make informed selections of healthcare organizations and professionals, particularly specialists. The public is dependent on state licensing to ensure that about 140 Missouri hospitals, 14,000 in-state physicians, 86,000 nurses and thousands of other licensed professionals provide safe care.

Executive directors from the state medical, nursing and pharmacy boards were appointed to the commission as ex-officio members and testified on the inadequacies in licensing laws that hamper their attempts to more effectively regulate these professionals.

Because of limited time, the commission could not investigate these areas as thoroughly as necessary. The seriousness and extent of these often long-standing problems need immediate study, possibly by an interim legislative committee, collaboration with professional associations and then legislative action.

At this time, the commission endorses one proposal:

- **The state should begin licensing "free-standing" medical specialty facilities that provide diagnostic services and perform such procedures as diagnostic imaging, heart procedures, gastrointestinal endoscopy and kidney dialysis.**

Procedures once thought to be safe only in a hospitals setting are now routinely performed in outpatient settings. A 2004 study[73] found that one in five

Americans receive outpatient treatment every month, but only eight people in 100 are hospitalized each month. The study also concluded – as have others - that serious medical errors occur more frequently in outpatient settings than in hospitals. Adverse events in the outpatient setting also have an impact upon healthcare costs. A 1999 study of hospital discharges in Utah and Colorado found that 57 percent of adverse events' costs resulted from outpatient incidents.[74]

The Missouri Department of Health and Senior Services ("DHSS") reported to the commission that many new types of outpatient providers, sometimes called "niche providers" or "medical specialty providers", are not regulated in Missouri. For example, DHSS regularly inspects and investigates complaints against hospital-based oncology services. In a free-standing clinic that provides oncology services, the state does not oversee equipment safety and facilities or compliance with the provider's own quality review. This same regulatory gap applies to many free-standing diagnostic services such as magnetic resonance imaging (MRI), endoscopy and cardiac catheterization as well as procedures such as lithotripsy, gamma knife and kidney dialysis.

These unlicensed healthcare organizations are providing services without public assurances of a minimum level of quality and safety.

Other regulatory action

- **Otherwise, the commission recommended that the General Assembly, where appropriate, allow licensing agencies to improve investigations of unsafe healthcare professionals, and take disciplinary action when it is evident that the provider was reckless, incompetent, impaired, negligent or abusive.**

Boards in the Department of Economic Development's Division of Professional Registration monitor licensees in medicine, nursing and pharmacy to maintain high professional standards and quality of care to safeguard the public health and safety.[75]

Each board gave the commission recommendations that they believe would strengthen their ability to improve patient safety.

The commission did not make specific recommendations for statutory changes, but these deficiencies affect all three boards and deserve legislative attention:

- **Only Missouri hospitals and ambulatory surgical centers are required to report to boards when they take final disciplinary action against a licensee.**

Missouri statutes require hospitals and ambulatory surgical centers to report such actions as reducing hospital privileges, placing the licensee on probation or terminating the employee for unsafe practices, but other healthcare organizations are not required to do so. For example, a nurse can violate professional standards, harm patients severely and move from nursing home to nursing home. The nursing homes are not required to notify licensing boards. The licensing boards are not given the opportunity to investigate and possibly take action against the licensee. Because nursing homes are not required to report, the law does not give nursing home administrators access to information about nurses whom the Board of Nursing is investigating; nursing homes unknowingly may hire personnel with histories of unsafe practice.

- **Legislation should clarify the meaning of 'final disciplinary action' because potential loopholes can allow even hospitals and ambulatory surgical centers to avoid notifying the board about employee discipline.**

All three licensing boards reported that Section 383.130-133, RSMo, requires only reports on *final* disciplinary action taken by the hospital or surgical center or resignations made to avoid potential disciplinary action. For example, if a consumer complains against a hospital's licensed nurse who then resigns his/her position at that hospital before any 'final' disciplinary, the hospital is not obligated to report to the board. Another healthcare organization

may then hire that nurse without any review by the board, and the new employer will not have access to information on the nurse's previous practice problems. The law essentially allows licensed personnel to use resignations to avoid disciplinary investigations.

- **The state licensing authorities need legal authority to share confidential investigation information to reduce duplication.**

DHSS noted that its review of a facility issue often involves separately licensed physicians, nurses and pharmacists. DHSS and the licensing boards need legal authority to share investigative information and reduce duplication. In those circumstances, the boards and DHSS should work in unison – each addressing regulations specific to their authority, but sharing expertise and information to correct the healthcare problem. For example, the DHSS may investigate a complaint that a hospital patient received the wrong medication. In that review, DHSS may find the hospital pharmacist did not follow hospital policy on dispensing. Today, DHSS must notify the Board of Pharmacy, which then undertakes a complete investigation. With clear authority to share, DHSS could provide all information that it gathered on pharmacy services with the board. The board then could build its investigation on what DHSS already had completed.

- **The state licensing boards do not have authority to deal swiftly with problem healthcare professionals.**

None of the boards can file an injunction, issue a restraining order, issue a writ of mandamus or suspend the license of a professional whose conduct is a clear and immediate danger to the public. The boards consequently cannot stop licensees from practicing when clear evidence of a criminal act has occurred that relates to the safe care of patients – until after the Administrative Hearing Commission has ruled.

The Board of Pharmacy in particular reported that more stolen or counterfeit, illegal Internet and imported drugs as well as adulterated and misbranded drugs are ending up in consumer hands. The board cannot act quickly to halt actions that may injure consumers of these unsafe drugs. While the boards recognize the need for due process, quick action to secure evidence and end distribution of dangerous drugs is necessary to protect patients.

Individual boards also presented information on their specific profession's licensing laws that deserve priority legislative study and action. They include:

- **Not all malpractice claims against physicians are transmitted to the Board of Registration for the Healing Arts**.

The Missouri Board of Registration for the Healing Arts (BHA), which oversees the practice of medicine in Missouri, indicated that it does not receive copies of all medical malpractice claims against physicians. State law requires all insurers and self-insured healthcare organizations to report malpractice claims to the Department of Insurance, which transmits those claims to the board. However, some self-insured organizations have failed to comply with the law since it passed in 1986; the Department of Insurance has no ability to fine or otherwise enforce the law against violators. BHA believes a patient care issue that grows into a malpractice lawsuit indicates a need for board review of the physician.

- **Physicians are not required to report criminal or employment disciplinary action to the medical board as soon as the incident occurs.**

BHA also testified that physicians must report any arrests, convictions, hospital disciplinary actions or impairment – but only when they apply for a license or two-year renewal. Unless physicians submit this information on a timely basis, the board generally does not know to investigate whether the physician can practice safely.

- **The Board of Nursing does not have access to criminal histories.**

The nursing board reported that it cannot obtain criminal history information from law enforcement agencies when investigating complaints. Without such legal access, the board may not know of criminal activity relevant to the safe functioning of a nurse and may continue to license a nurse who may jeopardize the safety of patients.

- **The nursing board cannot discipline nurses that fail to report.**

The Board of Nursing spends considerable time and expense trying to locate and legally notify licensees who have been disciplined, but fail to update the board on employment and residence and comply with licensing restrictions. These requirements may include training, rehabilitation, and/or prohibition from working in specified settings to assure the nurse provides safe patient care. The board by law cannot impose additional discipline in these circumstances.

Making safety improvements financially attractive to healthcare organizations

Commission recommendation: Missouri healthcare organizations and professionals should have incentives to participate in proven patient safety activities:

- **Healthcare payers should include incentives to foster patient safety initiatives in contracts for healthcare services.**
- **Liability insurers, including the new Missouri Medical Malpractice Joint Underwriting Association (JUA), should provide discounts for healthcare organizations and professionals that participate in patient safety activities.**

Costs as barriers to safety investments

The commission heard repeatedly that healthcare organizations and professionals want to improve their record of patient safety,[76] but face significant barriers, financial and otherwise. Improvements in patient safety often require healthcare organizations and professionals to incur up-front costs to modify the way care is delivered or managed. For example:

- The Leapfrog Group, a national consortium of employers promoting healthcare quality, encourages hospitals to implement computerized medical records.[77] Some studies project that computerized physician order entry (CPOE) could eliminate half of medication errors.[78] A 2003 report from the American Hospital Association and the Federation of American Hospitals, however, estimates CPOE could cost a 500-bed hospital $7.9 million in one-time investments, plus $1.35 million in annual operating expenses even if it already has a sophisticated computer system.[79] Web-based systems are available for a few thousand dollars per user, still a significant capital expenditure for a small physician office.[80]
- The Missouri Hospital Association estimates that dedicated patient safety staff would cost $100,000 annually in payroll expenses per hospital, although most hospitals will integrate this role with another position.[81] University of Missouri Healthcare, SSM Healthcare, Truman Veterans Hospital and Missouri Baptist Medical Center, all of which testified before the commission, have added patient safety officers and additional staff in some cases.[82]
- In 2001, the federal Agency for Healthcare Research and Quality recommended the use of ultrasound guidance to reduce morbidity from central venous catheter insertion. This equipment costs $11,000 to $16,000 per machine, plus the cost of needles, with a 400-bed hospital needing one to three machines.[83]
- Even independent development and establishment of an internal adverse event reporting system and staffing a patient safety committee could require a group practice to make significant expenditures or divert resources from other activities.

The current medical environment – with declining real reimbursement rates for many providers – creates enormous financial and operational pressures already. Investments in safety must compete with other projects that may promise more immediate savings and revenue to the healthcare organization. The commission believes more compelling financial incentives should exist to make these investments.

Savings

The cost of investing and maintaining safety innovations and programs should provide long-term economic savings.

For example, Kaiser Permanente – the national, not-for-profit firm that both insures and provides direct healthcare – is reportedly spending more than $2 billion on a computerized system built around the medical record. However, the firm expects this **system to pay for itself in three years.**[84] According to a study conducted in Hawaii, the estimated net benefit from using an electronic medical record for a five-year period was $86,400 per provider for primary care. Savings were found in drug expenditures, improved utilization of radiology tests, better capture of charges and decreased billing errors.[85]

But savings are not expected to manifest themselves in the short term. While Kaiser may recoup its investment in three years, the Hawaii study reviewed five years of activity after implementation of an electronic medical record. In the realm of insurers, employers and government programs that pay for most healthcare, the payout period may reach as far as 10 years.[86]

Healthcare organizations and professionals that pay for patient safety improvements may not themselves reap actual savings; in fact, greater safety may *reduce* future revenues. Prevention of errors represents true savings and efficiencies in global economic costs,[87] unlike some proposals for tort reform. Prevention of such errors avoids substantial extra healthcare costs, liability premiums, lost patient wages and quality of life, and diverted professional resources – providing savings to many parties besides the healthcare organizations that make the original safety investment.

This disconnect between upfront costs and benefits provides grounds for public policies that promote investment in patient safety improvement activities.

Safety incentives

Public programs and large employers have the most potential market leverage for making safety and, more broadly, quality a higher priority for healthcare organizations through financial incentives.

The state can lead in using purchasing power to make patient safety activities more financially attractive to providers. Missouri's Medicaid and MC+ programs have significant market power as a purchaser of healthcare services. In 2003, they spent more than $3.8 billion to cover more than 900,000 children and non-elderly adults (excluding nursing home services).[88] In fact, the state is a much larger purchaser of healthcare services in Missouri than the largest private health insurance companies – Healthy Alliance Life Insurance Company with 405,000 covered lives in the comprehensive medical market[89] and Group Health Plan with 159,000 commercial HMO members.[90]

The MC+ program and the fee-for-service Medicaid pharmacy program both use competitive contracting systems for healthcare services. These contracts already contain requirements to further state policy goals. For example, all contractors must assure that 10 percent of their operating activities are carried out through minority- or female-owned businesses. Other contracting conditions are handled as preferred items, but not necessarily required. For example, managed care companies contracting with MC+ can earn preferential treatment if federally qualified or rural healthcare clinics are included in provider networks. A similar mechanism could reward participation in patient safety improvement activities.

The commission cautions that because the state largely contracts with insurers rather than providers, **any funds awarded for participation in patient safety improvement activities must flow through to healthcare organizations and professionals that incur patient safety costs to act as actual incentives**. For example, contract awards can create incentives if they prefer insurers that pay higher reimbursement rates for providers that participate in proven safety initiatives.

The Missouri Consolidated Healthcare Plan (MCHCP) similarly contracts on a much smaller scale to provide benefits to state and local government employees. MCHCP purchases healthcare coverage for about 95,000 persons[91] with a budget of about $25.6 million for 2004 and 2005.[92] Similar to the Medicaid contracting process, MCHCP solicits competitive bids from private insurers. Contracts are awarded based in part on each company's response to MCHCP's policy requirements.

Employers – which benefit financially when their workers avoid errors in medical care – can play a role similar to state government by offering incentives for providers to improve safety. In fact, once health plans and providers accommodate state contract incentives for patient safety, it becomes easier to for all businesses to use the same approach.

The commission cautions against using purchasing power to penalize healthcare organizations and professionals, mainly because of the potential effects on the access of low-income Missourians to healthcare. Excluding or penalizing healthcare organizations and professionals for failure to implement patient safety improvement processes could result in loss of providers from the Medicaid and MC+ programs, causing greater difficulty for persons who already have access problems. Additionally, both state and federal access standards exist for HMOs in Missouri. Punitive contracting provisions could cause double problems – for patients in obtaining healthcare and for HMOs in meeting access standards.[93]

The use of government and business contracting to promote patient safety improvements is not yet widespread. Among the ways other states and groups encourage patient safety and related quality initiatives:

- The Georgia Medicaid program and Georgia's state employee health plan, as two of the largest purchasers in the state, require in their contracts that participating hospitals be involved in the lone statewide patient safety improvement initiative, the Georgia Partnership for Health and Accountability.[94]
- The Leapfrog Group encourages employers, as major purchasers of healthcare services, to "recognize and reward providers that work to protect patients."[95] For example, Leapfrog promotes the incentive approach of member General Motors in encouraging employees to choose higher-performing health plans and reducing the out-of-pocket expenses of employees who select higher-performing hospitals. The program has been successful in steering employees into those plans.[96]
- The Midwest Business Group on Health, a smaller coalition of regional public and private employers, serves as a group purchaser for member employers and tracks and compares HMO performance on patient safety.[97]
- The Bridges to Excellence Physician Office Link, a pay-for-performance project, allows physician practices to qualify for bonuses based on implementation of quality and error-reduction programs. Physicians can earn up to $50 per year for each patient covered by a participating employer or plan. A report card for each physician office describes its performance on the program measures and is made available to the public.[98] Bridges to Excellence pays individual doctors with funds from participating employers and a $330,000 grant from the Robert Wood Johnson Foundation.[99]
- Mercy Health Plans, a Missouri-based HMO, offers incentives to participating surgeons for using an Internet-based educational tool, which provides information on a wide range of common surgical procedures, as part of informed consent and to track outcomes and patient satisfaction. Mercy provides access to this educational tool through its website. Surgeons receive higher reimbursement rates for using the educational program in their offices.[100] Several large employers that participate in the St. Louis Area Business Health Coalition also make the product available to their employees.

Medical malpractice insurance incentives

Patient safety programs reduce systemic or institutional errors that generate malpractice litigation and awards and consequently increase costs for liability insurers and policyholders. Such programs also should reduce malpractice litigation that results not from actual errors, but communication breakdowns and other non-negligent factors; while insurers are not liable for damages in non-negligent cases, they may incur substantial defense costs. Dr. Gerald Hickson of Vanderbilt University testified on his research that found 44 percent of malpractice litigation results from failure, usually preventable, to communicate with patients about unexpected adverse outcomes.[101]

The commission also heard testimony from officials of several Missouri institutions on the value of immediately disclosing errors and including patients in the process of determining the root cause of adverse events.[102] Representatives from Harry S. Truman Memorial Veterans' Hospital and Fortisan Group testified that patient disclosure results in reduced litigation, even if malpractice legally occurred. After the Veterans Administration required disclosure of medical errors to patients and analysis of medical errors, a measurable drop occurred in payouts for medical malpractice; some Veterans Administration hospitals have experienced a decrease of as much as 90 percent.[103]

Yet liability insurance discounts for participation in patient safety improvement activities appear to have declined. In 1999, medical economist Michael Parrish noted that medical malpractice insurance companies were moving away from offering discounts for attendance at risk management seminars on the grounds that they weren't effective in improving practice. One insurer cited attendees who signed up for the discount, but left the seminars early.[104] The disappearance of discounts in the late 1990s may have occurred because they were gratuitous. Heated competition for market share drove premiums below costs, according to the Missouri Department of Insurance. In effect, carriers were discounting every policy, without regard to risk.

Sixteen companies in Missouri actively offer medical malpractice insurance, including the new Medical Malpractice Joint Underwriting Association.[105] Two of the four largest carriers offer discounts for patient safety improvement activities.

Large hospitals and health systems have greater capacity to self-insure and directly reap any benefit from the investments made in patient safety. The Missouri Hospital Plan (MHP), a licensed medical malpractice insurance company, focuses on coverage for small to medium-size rural and community hospitals and ranks as the largest carrier for fully insured hospitals. While MHP doesn't provide a discount on liability premiums for patient safety activities, the company offers free seminars and continuing medical education credits for patient safety. As a mutual company, a dividend is paid to members if losses are reduced below projections. Because of its market position, MHP could become a leader in safety-related innovations for other malpractice carriers in the professional liability market for hospitals.

Healthcare organizations and professionals likely would wait years to gain insurance benefits from safety investments under current conditions. Most insurers do not recognize loss-prevention programs until the data firmly measure the savings – often over five to seven years for 'long-tail' lines of coverage like malpractice and workers compensation – regardless of the decline in risk.

Mandatory premium discounting to promote safety programming has precedent in Missouri.

Missouri's insurance industry now routinely grants employers engaged in safety programs discounts on their workers compensation premiums. But a decade ago, to guarantee that employers had a financial return and provide a one-time 'jump start' for safety engineering investments, the Missouri General Assembly required such discounts for businesses participating in state-certified programs.

Today, a 5 percent premium credit is typical for those employers who meet a workers compensation insurer's safety criteria although insurers are free to provide credits up to a maximum of 25 percent for safety and other factors combined. Safety programs and engineering are among the reasons Missouri has seen a substantial decrease in the workers' compensation claims over the past decade.

Outside Missouri, at least a few medical malpractice discount programs are offered:

- Pennsylvania has begun requiring medical malpractice insurance discounts for healthcare organizations and professionals that participate in state-certified safety improvement activities. Pennsylvania state agencies establish the actuarial value of patient safety improvements and certify patient safety improvement programs. The state reimburses insurers from a 25-cent increase in the tobacco tax as an offset against each insured provider's malpractice premium. This "abatement" amounts to up to 100 percent of otherwise required provider licensure fees.[106] So far 33,000 physicians have applied for the abatements.
- Tennessee's Volunteer State Mutual Insurance Company offers a 10 percent annual premium discount for physicians who attend crew resource management safety seminars.[107]
- -In June 2003 the Controlled Risk Insurance Company (CRICO, which does not operate in Missouri) approved a voluntary program that gives obstetricians a 10 ten percent malpractice premium rate reduction if they complete specific risk reduction activities as part of its patient safety initiative.[108]
- Combined with a practice review, policyholders of the Texas Medical Liability Trust – that state's largest insurer – may receive a 2.5 percent risk management discount for the use of electronic medical records and electronic prescribing. Eligibility is contingent upon documented use of a program for a minimum of one year.[109]
- The commission recommends that the proposed Missouri Center for Patient Safety and the Missouri Department of Insurance encourage the state's private medical liability carriers and the JUA to discount premiums of healthcare organizations and professionals who participate in proven patient safety activities.

Other incentives

Non-financial incentives also can help reward healthcare organizations and professionals for participating in patient safety activities. These programs recognize the leadership, innovation and practicality of implementing patient safety practices:

- Georgia's Partnership for Health and Accountability (PHA) recognizes organizations with its Quality and Patient Safety Award.[110] The PHA says recognition helped encourage more hospitals to participate – especially small critical-access hospitals. Small hospitals were skeptical of their ability to contribute meaningfully to other hospitals.[111] One award winner was a small rural hospital that was unable to provide a staff pharmacist after 4:30 p.m. or on weekends, but reduced after-hours dispensing errors by purchasing a pharmacy cart and training staff on its use.[112]
- The federal Malcolm Baldrige National Quality Award is given by the president of the United States to businesses — manufacturing and service, small and large — that are outstanding in seven areas: leadership, strategic planning, customer and market focus, information and analysis, human resource focus, process management, and business results. Three awards are given each year.[113] In 2002, SSM Healthcare of St. Louis became the first healthcare organization to win the award, in recognition of its patient safety programs.[114] St. Luke's Hospital in Kansas City won the award in 2003.

- The American Hospital Association's McKesson Quest for Quality Prize℠ provides monetary and non-monetary awards for commitment to highly reliable, exceptional quality, patient-centered care.[115] Missouri Baptist Medical Center in St. Louis won this national award in 2002, the first year it was offered, for leadership and innovation in the creation of a culture of patient safety.[116]

■ **The commission recommends that the proposed Missouri Center for Patient Safety sponsor such award programs to bring public recognition to successful healthcare organizations and increase the viability for patient safety programs statewide.**

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Dictionary of Terms

The dictionary items define the intent of language in this document and may not agree with statutory definitions. The general source for definitions is included in italics within parentheses.

Action plan

This result of root cause analysis addresses system and process deficiencies; improvement strategies are developed and implemented. The plan includes outcome measures to indicate that system and process deficiencies are effectively eliminated, controlled or accepted. The action plan aims to find ways to prevent repeat of adverse events or close calls. *(VA National Center for Patient Safety)*

Adverse event

Untoward incidents, therapeutic misadventures, iatrogenic injuries or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other facility. Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.). *(VA National Center for Patient Safety)*

AHRQ

Agency for Healthcare Research and Quality. A federal agency under the Department of Health and Human Services, established to improve the quality, safety, efficiency and effectiveness of health care for all Americans.

Best practices

The processes, practices and systems identified in public and private organizations that performed exceptionally well and are widely recognized as improving an individual's or organization's performance and efficiency in specific areas. *(U.S. General Accounting Office)*

Claim/malpractice claim

A legal action filed on behalf of a patient against a healthcare professional or organization in which there is an alleged claim for damages occurring during the course of treatment of that patient by the healthcare professional or organization.

Culture of safety

A culture where those who manage and operate the system have current knowledge about the human, technical, organizational and environmental factors that determine the safety of the system as a whole. Four critical subcomponents of a safety culture include: 1) a reporting culture where people are prepared to report errors and near-misses; 2) a just culture where people are encouraged, even rewarded, for providing essential safety-related information, but in which they are also clear about where the line must be drawn between acceptable and unacceptable behavior; 3) a flexible culture capable of adapting effectively to changing demands; and 4) a learning culture possessing the willingness and competence to draw the right conclusions from its safety information system and to implement major reforms when needed. *(Reason, J.)*

Evidence-based medicine

The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. *(Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB)*

Failure mode effects analysis

A systematic way of examining a design prospectively for possible ways in which failure can occur. It assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur. *(JCAHO)*

Final disciplinary action

A final action directed against a healthcare professional by any entity, including, but not limited to, a governmental authority, a healthcare facility, an employer or a healthcare professional association (international, national, state or local). Such actions would result in, for example, license revocation, suspension, restriction, non-renewal or denial of a right or privilege and may be voluntary or involuntary.

Healthcare failure mode effects analysis

A systematic method of identifying and preventing product and process problems before they occur. The use of a multidisciplinary team to proactively evaluate a health care process. *(VA National Center for Patient Safety.)*

Healthcare organization

Any entity or organization including, but not limited to, a hospital, a health maintenance organization, group or single medical practice, home health organization, nursing home, pharmacy, surgery center, therapy center, health science center, healthcare professional school, governmental health clinic, professional society, hospital district, hospital authority, ambulatory surgery center, any free standing facility that provides imaging services including computerized tomography, magnetic resonance imaging and positron emission tomography, radiation therapy, oncology, heart procedure including cardiac catheterization, lithotripsy, gamma knife, gastrointestinal, endoscopy and kidney dialysis services, or other healthcare facility or entity whose primary function is to provide healthcare services.

Healthcare professional

An individual who is approved to work in the healthcare field, including but not limited to physician, dentist, podiatrist, chiropractor, optometrist, psychologist, pharmacist, all nurse designations, physical therapist, respiratory therapist, healthcare professional in training or any other person who provides healthcare services.

Human factors engineering

Understanding and optimizing how people use and interact with technology. *(U.S. Department of Agriculture)*

Interdisciplinary team training/crew resource management/crew training

Teamwork training about the limiting factors of human performance (such as fatigue and stress), the nature of human error, and behaviors that are countermeasures to error, such as leadership, briefings, monitoring and cross checking of communication and performance, decision making, and review and modification of plans. The training includes skills on how to use all available resources - information, equipment, and people - to achieve safe and efficient operations. *(Helmreich, RL.)*

JCAHO

Joint Commission on Accreditation of Healthcare Organizations. It is an independent, not-for-profit organization, established more than 50 years ago, governed by a board that includes physicians, nurses, and consumers. JCAHO sets the standards by which health care quality is measured in America and around the world. *(JCAHO)*

Medical error

The failure of a planned action to be completed as intended (i.e.: error of execution) or the use of a wrong plan to achieve an aim (i.e.: error of planning). *(Reason, JT, Kohn L, Corrigan J, and Donaldson M)*

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Near-miss

An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. *(Quality Interagency Coordination Task Force)*

Patient safety

The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care. These events include errors, deviations, and accidents. *(Cooper JB, Gaba DM, Liang B, Woods D, Blum LN.)*

Patient safety data

Data related to medical events that resulted or could have resulted in patient harm that includes but is not limited to data on near-misses, sentinel events and adverse events. It also includes data related to solutions to the problem that contributed to the occurrence of the medical error and root cause analysis data.

Patient safety officer

A person or persons who ensure the healthcare organization incorporates and utilizes methods to improve all aspects of patient safety and promotes a culture that perceives safety as a priority. They gather and disseminate appropriate information about systemic organizational vulnerabilities and analyze the human, organizational and systems factors, which contribute to adverse events. They analyze clinical processes and develop strategies to maximize their safety, efficacy and efficiency. They develop and implement medical error reduction strategies internally in collaboration with external sources.

Peer review committee

Any committee or organization established by a healthcare professional or healthcare organization that engages in peer review activities.

Peer review/peer review activities

Investigations and evaluations of:

- quality and efficiency of services performed by a healthcare professional or healthcare organization.
- qualifications, competence and performance of a healthcare professional or healthcare organization.
- whether services provided by a healthcare professional or healthcare organization were professionally indicated or were performed in conformance with the applicable standard of care.
- whether the cost of services provided by a healthcare professional or healthcare organization was reasonable.
- healthcare professional's or healthcare organization's compliance with applicable policies, procedures, standards, laws, rules or regulations.
- complaint relating to a healthcare professional or healthcare organization.

It also includes:

- practice analysis of inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review, and claims review.
- the establishment and enforcement of guidelines designed to keep within reasonable bounds the cost of health care.

Quality improvement activities

Evaluating matters relating to the care and treatment of patients in order to reduce morbidity and mortality and in order to improve the quality of health care through the review of process practices, training and experience, patient cases or conduct of healthcare professionals. Quality improvement activities include the collection of data and information used for monitoring and evaluating the quality and appropriateness of care provided to patients, as well as patient outcomes, so that important problems and trends in the delivery of care are identified and steps are taken to correct such problems.

Risk management

Clinical and administrative activities undertaken to identify, evaluate and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself. *(JCAHO)*

Root cause/root cause analysis (RCA)

A process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. RCA has the following characteristics:

- The review is interdisciplinary in nature with involvement of those closest to the process.
- The analysis focuses primarily on systems and processes rather than individual performance.
- The analysis digs deeper by asking *what* and *why* until all aspects of the process are reviewed and all contributing factors are identified (progressing from looking at special causes to common causes).
- The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes or systems that would improve performance and reduce the risk of event or close call recurrence. *(VA National Center for Patient Safety)*

Sentinel event

An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. *(JCAHO)*

System failure analysis

Using prompt, intensive investigation followed by multidisciplinary systems analysis...to [uncover] both proximal and systemic causes of errors.... It is based on the concept that although individuals make errors, characteristics of the systems within which they work can make errors more likely and also more difficult to detect and correct. Further, while individuals must be responsible for the quality of their work, focusing on systems rather than on individuals will eliminate more errors. It substitutes inquiry for blame and focuses on circumstances rather than on character. *(Leape LL, Bates DW, Cullen DJ, et.al.)*

Tools of patient safety

Processes, materials and resources that are based upon scientific information and will assist patients and healthcare professionals in putting safety into everyday activities: e.g., root cause analysis, healthcare failure mode effects analysis, human factors engineering and interdisciplinary team training and consumer publications.

Presentations
Missouri Commission on Patient Safety

The Missouri Commission on Patient Safety heard from a broad range of witnesses, many of which are considered trendsetters and authorities in their fields, while deliberating on modern approaches to error prevention over seven months.

The aviation and nuclear industries presented their advanced safety programs, identifying effective approaches that might transfer to the healthcare field.

The commission learned about innovative approaches for improving patient safety used in the SSM Health Care system, Missouri Baptist Medical Center in St. Louis, University of Missouri Health Care in Columbia, and Children's Mercy Hospital in Kansas City. Graphic Surgery demonstrated its package of patient education information, which is available to individual physicians for patients to better participate in their healthcare.

Representatives of Vanderbilt University, the Citizens Advocacy Center in Washington, D.C., and others testified on physician and nurse remediation programs to correct high-risk behaviors. Medical and nursing educators spoke on improvements in healthcare professional curriculum and continuing education on patient safety.

Vi Naylor, executive vice president of the Georgia Hospital Association, outlined that state's *Partnership for Health and Accountability*, and Missouri Department of Insurance staff provided insights on other states' efforts to improve patient safety. Such national organizations as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Leapfrog Group, and the Veterans Administration hospital systems gave the commission an overview of national efforts on error prevention.

The commission appreciates the time and effort that all presenters contributed to this process.

Sponsors for presentations included the Missouri Hospital Association, Walgreens, SSM Health Care, MissouriPRO (the state's Medicare quality improvement organization) and the Department of Insurance.

The commission also appreciates the administrative support provided by the Department of Insurance staff: Melissa Becker, Carlin Blair, Linda Bohrer, Carrie Couch, Goldie Holzer, John Korte, Kevin Lanahan, Randy McConnell, Albert Shoemaker, Diane Springs, Bryan Trabue, and Molly White.

October

- Department of Health and Senior Services — Duties/data collection/regulatory authority (Lois Kollmeyer, assistant director)
- Board of Registration for the Healing Arts — Duties/regulatory authority/data collection (Tina Steinman, executive director)
- Board of Pharmacy — Duties/regulatory authority/data collection (Kevin Kinkade, executive director)
- Board of Nursing — Duties/regulatory authority/data collection (Lori Scheidt, executive director)
- Department of Insurance medical malpractice report/data collection (Scott Lakin, director, and Brent Kabler, research supervisor)

November

- Review of other states' patient safety commissions (Linda Bohrer, market regulation director, Department of Insurance)
- Medical malpractice case review by DHSS (Kollmeyer), Board of Healing Arts (Dr. Barry Spoon, board member and commissioner), University of Missouri Health Care (Kathryn Nelson, commissioner) and Kansas City attorney Derek Potts
- Root cause analysis (Tim Anderson, patient safety manager, Truman Memorial Veterans Administration Hospital)
- Missouri Baptist Medical Center patient safety activities (Nancy Kimmel, commissioner)
- Medical malpractice litigation (Tom Cartmell and Ken Vuylsteke, commissioners)

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December

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO) – mission and activities (Noelle Brown, associate director of state relations)
- Missouri Hospital Association — its approach to patient safety issues with member hospitals (Becky Miller, vice president, quality and regulatory advocacy)
- Other states' patient safety commission activities (Bohrer)
- Pharmacists' view of patient safety (Audrey Hudson Neely, professional affairs manager, Walgreens)

January

- Patient advocate perspective (Ashley Allen, executive director, Missouri Watch)
- University of Missouri Health Care error system (Kathryn Nelson, commissioner)
- Georgia Partnership for Health and Accountability (Vi Naylor, executive vice president, Georgia Hospital Association)
- Patient education system (Dr. Patricia Gelnar, president, Graphic Surgery)
- Nuclear energy safety system, (Mark Elliot, vice president, Team WD)
- Nurses view on patient safety (Kathy Ballou, assistant professor, University of Missouri-Kansas City School of Nursing)
- SSM's patient safety programs (Dr. Paul Convery, chief medical officer, SSM Health Care)
- Aviation crew training, (Jeff Hill, president, Crew Training International, and Laurel Destins, clinical nurse specialist, University of Missouri Health Care)

February

- Physician remediation research (Dr. Gerald Hickson, associate dean of clinical affairs, Vanderbilt University Medical Center)
- The Leapfrog Group—mission and activities (Louise Probst, St. Louis Area Business Health Coalition)
- Prep 4 Patient Safety/doctor and nurse remediation project (David Swankin, president, Citizens Advocacy Center)
- Peer review law research (Ken Vuylsteke, commissioner, and Rex Burlison, chief counsel, Missouri Attorney General's Office)

March

- Medical school curriculum changes related to patient safety (Dr. Betty Drees, dean, University of Missouri-Kansas City Medical School)
- Private practice — patient safety initiatives in the doctor' office & outpatient setting (Dr. Robert Phillips, assistant director, The Robert Graham Center)
- A psychologist's approach to physician remediation (Dr. Jim Dugan, Fortisan Group LLC)
- The Utah-Missouri Study — the findings (Sue Elder and Garland Land, section directors, DHSS)

April

- The legal impact of peer review statutes on hospital investigations (Sally Surridge, vice president/general counsel, Children's Mercy Hospital, Kansas City)

Time not dedicated to presentations at these meetings allowed for working sessions. Four meetings were exclusively working meetings for the commission, as were several telephone conferences.

Additional source material on presentations is available at the Missouri Commission on Patient Safety website, www.insurance.mo.gov/aboutMDI/issues/patsafety/index.htm

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State patient safety websites

- California Health Care Foundation: Patient Safety - *URL: www.chcf.org/topics/index.cfm?topic=CL143*
- California Institute for Health Systems Performance - *URL: www.cihsp.org/cgi-bin/default.asp*
- Chicago Patient Safety Forum - *URL: www.chicagopatientsafety.org/*
- Colorado Patient Safety Coalition - *URL: www.coloradopatientsafety.org/*
- Georgia Partnership for Health and Accountability - *URL: www.gha.org/pha/*
- Healthcare Association of Hawaii's Patient Safety Task Force - *URL: www.hah.org/000131d/hah.nsf/6ad900162da985950a2565e1007bb332/4a64cd0d34d973e70a256c29007686ef?OpenDocument*
- Healthy Florida Foundation - *URL: www.healthyfloridafoundation.org/*
- Illinois Hospital Association - *URL: www.ihatoday.org/public/patsafety/*
- Indiana Commission On Excellence In Health Care Patient Safety Subcommittee - *URL: www.indylaw.indiana.edu/centers/clh/PSSek.htm*
- Iowa Department of Public Health Patient Safety Program - *URL: www.idph.state.ia.us/patient_safety/default.html*
- Iowa Hospital Association - Improving Patient Safety Best Practices - *URL: www.ihaonline.org/publications/bestpractices.pdf*
- Kentucky Medical Association Patient Safety Task Force - *URL: www.kyma.org/Patient Safety.php*
- Madison Patient Safety Collaborative - *URL: www.madisonpatientsafety.org/*
- Maryland Patient Safety Center - *URL: www.marylandpatientsafety.org/*
- Massachusetts Coalition for the Prevention of Medical Errors - *URL: www.macoalition.org/*
- Michigan Health and Safety Coalition - *URL: www.mihealthandsafety.org/*
- Minnesota Alliance for Patient Safety - *URL: www.mihealthandsafety.org/*
- Missouri Commission on Patient Safety - *URL: www.insurance.mo.gov/aboutMDI/issues/patsafety/*
- New Jersey Health Care Quality Institute - *URL: www.njhcqi.org/*
- New York Center for Consumer Health Care Information - Patient Safety Center - *URL: www.health.state.ny.us/nysdoh/healthinfo/patientsafety.htm*
- Ohio Patient Safety Institute - *URL: www.ohiopatientsafety.org/*
- Ohioans FiRxst - *URL: www.ohiopatientsafety.org/*
- Patient Safety In Washington, DC - *URL: www.dcpatientsafety.org/*
- Pharmacy Society of Wisconsin - *URL: www.pswi.org/professional/standards/*

- Pennsylvania Patient Safety Collaborative - *URL: www.papatientsafety.net/*
- Pennsylvania Patient Safety Authority - *URL: www.psa.state.pa.us/psa/site/default.asp*
- PULSE America.Org - (Persons United Limiting Substandards and Errors in Healthcare) - *URL: www.pulseamerica.org/*
- San Diego Center for Patient Safety - *URL: www.cybermed.ucsd.edu/SDCPS/Home.html*
- Safer California Healthcare - The Strategic Alliance for Error Reduction (SAFER) - *URL: www.safer.healthcare.ucla.edu/*
- University of Michigan's Patient Safety Enhancement Program (PSEP) - *URL: www.med.umich.edu/psep/index.htm*
- Utah Patient Safety Initiatives - *URL: www.health.utah.gov/psi/*
- Virginians Improving Patient Care and Safety - *URL: www.vipcs.org/*
- Washington Patient Safety Coalition - *URL: www.wapatientsafety.org/*
- Wisconsin Patient Safety Institute - *URL: www.wpsi.org/*

Additional resources:

- Agency for Healthcare Research and Quality - *URL: www.ahrq.gov/clinic/ptsafety/*
- Children's Mercy Hospital and Clinics - *URL: www.cmh.edu/*
- Fortisan Group LLC - *URL: www.fortisan.com/*
- JCAHO – Joint Commission on Accreditation of Healthcare Organizations - *URL: www.jcaho.com/*
- The Leapfrog Group - *URL: www.leapfroggroup.org/*
- Missouri Hospital Association - *URL: www.web.mhanet.com/*
- Missouri Board of Healing Arts - *URL: www.pr.mo.gov/healingarts.asp*
- Missouri Board of Nursing - *URL: www.pr.mo.gov/nursing.asp*
- Missouri Board of Pharmacy - *URL: www.pr.mo.gov/pharmacists.asp*
- Missouri Department of Health and Senior Services - *URL: www.dhss.mo.gov/*
- Missouri Department of Insurance - *URL: www.insurance.mo.gov/*
- Missouri Pro - *URL: www.mpcrf.org/*
- Missouri Watch, Inc. - *URL: www.missouriwatch.net/*
- National Academy for State Health Policy - *URL: www.nashp.org/_docdisp_page.cfm?LID=B8A71AAA-7236-11D6-BD1200A0CC76FF4C*

- National Hospital and Academic Medical Center Patient Safety Resources - *URL: www.vipcs.org/resources/Notable*
- National Patient Safety Foundation - *URL: www.npsf.org/*
- PREP4 - *URL: www.cacenter.org/*
- Robert Graham Center - *URL: www.aafppolicy.org/*
- University of Missouri Health Care - *URL: www.muhealth.org/~psn*
- University of Missouri-Kansas City School of Nursing - *URL: www.umkc.edu/html/acjobs/nurse.html*
- VA National Center for Patient Safety - *URL: www.va.gov/ncps/index.html*
- Vanderbilt Center for Patient and Professional Advocacy - *URL: www.mc.vanderbilt.edu/cppa*
- Walgreen's - *URL: www.walgreens.com/*